ADVANTAGE

SERIES OF FOOD SAFETY PROGRAMS

Advantage HACCP

Version 3.0

For Food Processing Operations

Book 3

Ministry of Agriculture,
Food and Rural Affairs

Ontario

This book is part of the *Advantage Series of Food Safety Programs* for Food Processors in Ontario. Previously, the program materials included:

- *Advantage* Program Manual V2.0 which contained *Advantage Good Manufacturing Practices (GMP), Advantage Hazard Analysis Critical Control Point (HACCP)* and *HACCP Plus* information
- *Advantage* Guidebook V1.0 which contained general information on food safety, developing your GMP program, developing HACCP plans and certification.

This book is part of a series that replaces the previous program manual and guidebook. In this series, standards from the program manual and guidance elements from the guidebook are combined. Each level of the program (GMP, HACCP and HACCP Plus) will have its own manual. The series of books will also include an introduction manual and an audit preparation manual.

The series was written to give food processors a step-by-step approach to implementing food safety. Processors can request manuals as they need them depending on what phase of their food safety program they are working on. The manuals also provide many more examples for users.

Authors
Food Safety and Traceability – Food Industry Unit Staff
Food Safety Programs Branch
Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA)

Need more information?

Contact:
Advantage Series of Food Safety Programs for Food Processors
Ontario Ministry of Agriculture, Food and Rural Affairs
Food Safety Programs Branch
1 Stone Road West
Guelph, Ontario N1G 4Y2

Toll Free: 1 866 641-3663 (FOOD)
Email: advantage@ontario.ca
Web site: *www.ontario.ca/haccp*

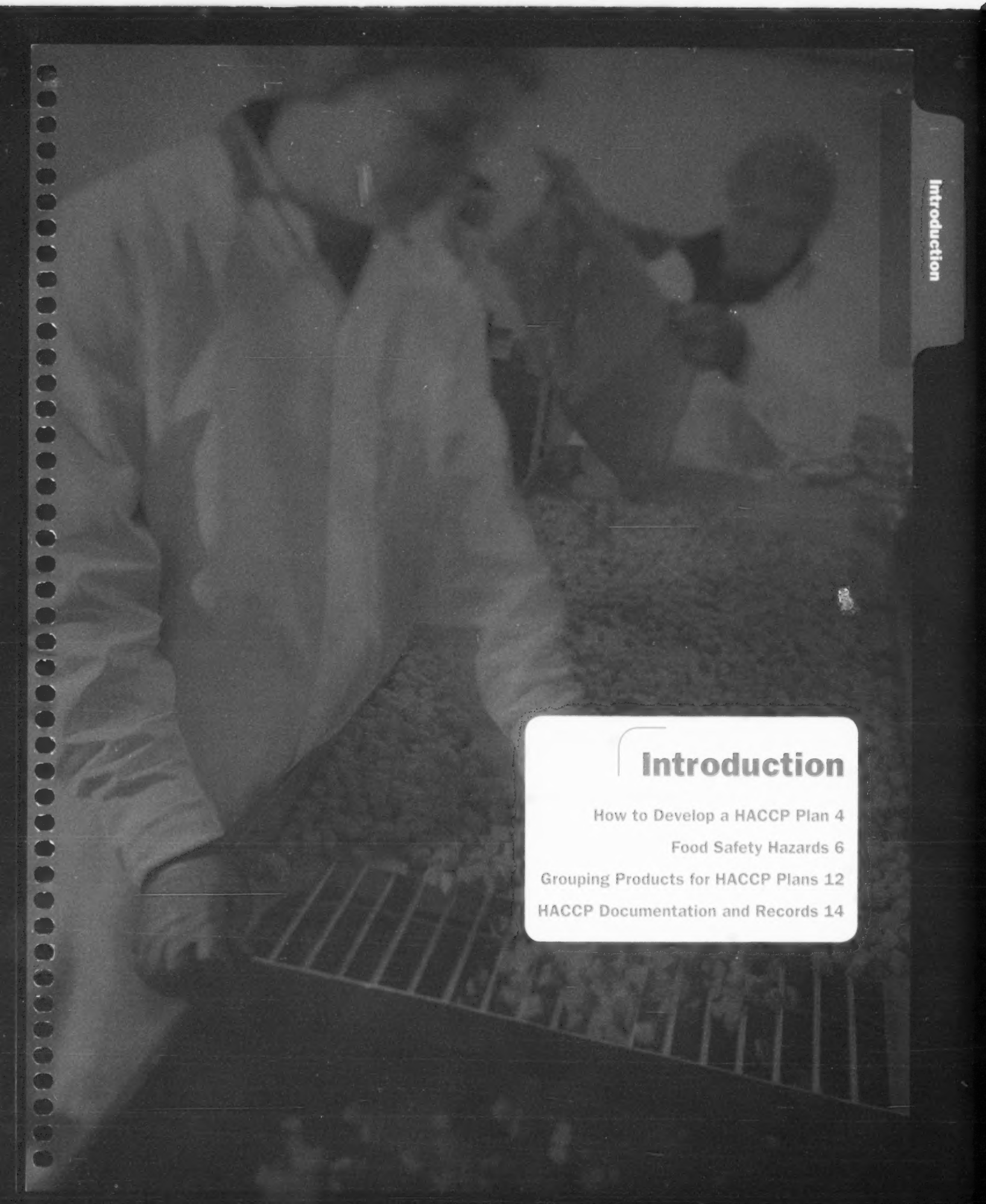
Version Date: March 2010

Aussi disponible en français.

Published by the Ontario Ministry of Agriculture, Food and Rural Affairs

Toronto, Canada
ISBN 978-1-4435-0720-2
05-2009-1,000

Table of Contents



Introduction

Introduction

Welcome to *Advantage HACCP*. This book is designed to assist you in developing your HACCP Plans.

Before proceeding with HACCP Plans, Good Manufacturing Practices (GMPs) must be in place. For more information on GMPs, please refer to *Advantage GMP* Book 2.

What is HACCP?

HACCP (pronounced HASSIP) stands for Hazard Analysis and Critical Control Point. HACCP is:

- a science-based, food safety system
- used to help ensure processing of safe food products
- internationally recognized as the primary means for enhancing food safety
- used around the world
- focused on preventing problems before they occur, rather than trying to detect failures through final product testing

HACCP Plans are designed to prevent, eliminate or reduce to an acceptable level potential biological, chemical and physical food safety hazards, including those caused by cross-contamination.

HACCP Plans are designed to control hazards directly related to the finished product, ingredients or process steps, which are not controlled by Good Manufacturing Practices (GMPs).

HACCP and the Codex Alimentarius Commission

HACCP has been standardized internationally by the Codex Alimentarius Commission, known as Codex. Codex was created by the Food and Agricultural Organization and the World Health Organization of the United Nations. Codex develops food standards, guidelines and related texts. To reduce problems with differing interpretations of how to apply HACCP principles, Codex produced internationally agreed on guidelines. These guidelines are used around the world in the development of HACCP systems. *Advantage HACCP* is based on Codex guidelines.

How to Develop a HACCP Plan

To develop your HACCP Plan(s), you need an understanding of:

- all products processed in your facility
- the characteristics important to food safety for each product (e.g. pH, a_w)
- all ingredients, packaging materials and processing aids used in your facility
- the processes used to manufacture all of your products
- the biological, chemical and physical food safety hazards associated with your products, ingredients, packaging materials, processing aids, processing steps and each area of your facility
- how each area of your facility is utilized
- the flow of people, finished products, ingredients, allergens, raw products, chemicals, packaging materials and waste through your facility

HACCP Plans are developed through a process of hazard analysis to determine hazards that are significant to food safety. Control measures are then put in place at specific processing steps, and monitored for effectiveness. If a control measure fails, actions are taken to correct the failure.

HACCP Forms

To develop a HACCP Plan, eight forms must be completed in sequence.

Form 1 – Product Description

Form 2 – Incoming Materials (Ingredients, Processing Aids, Packaging Materials)

Form 3 – Flow Diagram

Form 4 – Facility Schematic

Form 5 – Hazard Description and Critical Control Point Determination

Form 6 – Flow Diagram with Critical Control Points

Form 7 – Uncontrolled Hazards

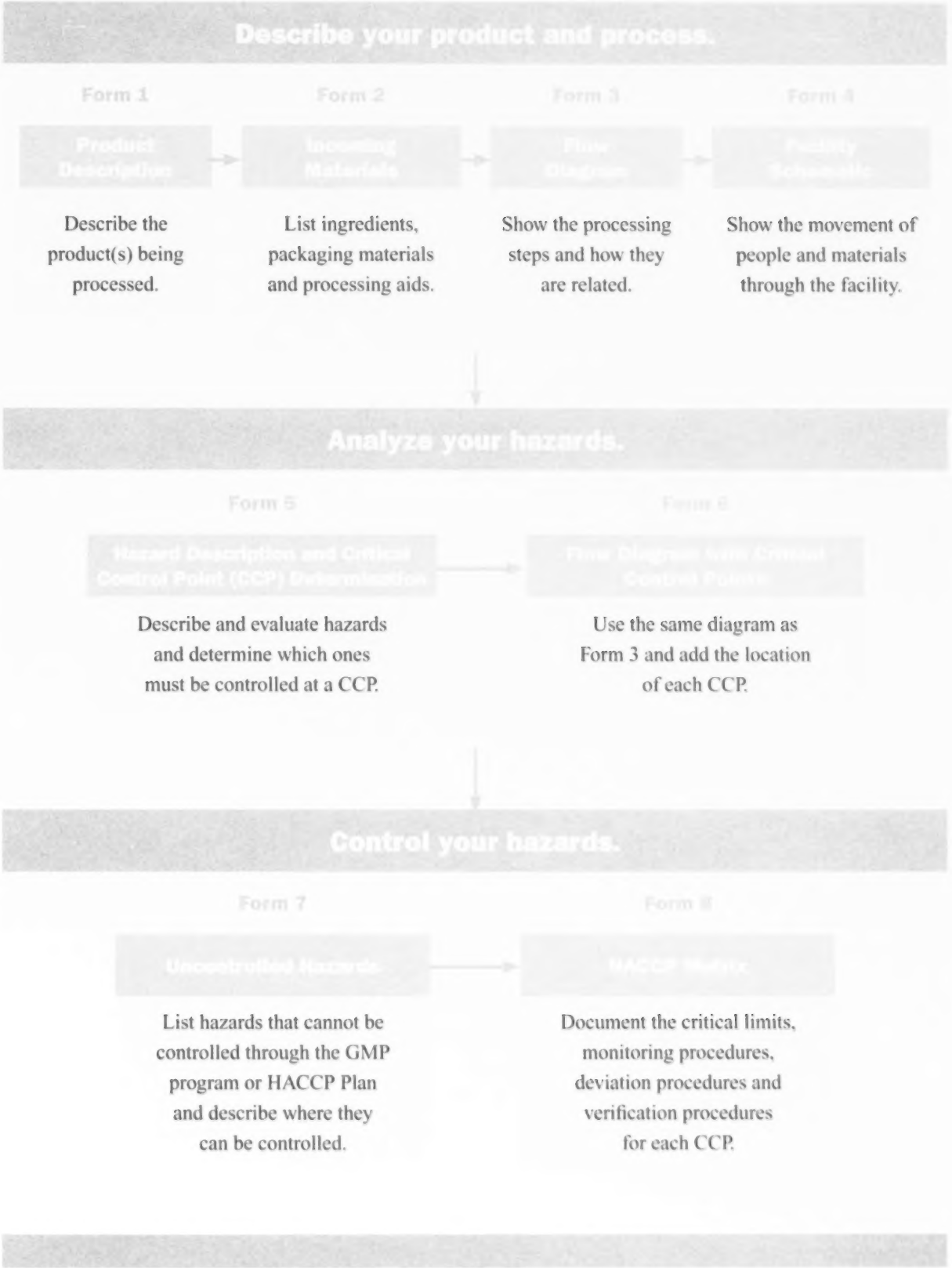
Form 8 – HACCP Matrix

Visit our website at www.ontario.ca/haccp to obtain electronic copies of these forms.

Each form is explained in detail throughout this book, including examples of how to properly complete each form.

Figure 1 shows an overview of the process to develop a HACCP Plan.

Figure 1. *Advantage HACCP* overview



Food Safety Hazards

What are the hazards?

Food safety hazards can make food unsafe to eat and cause illness, injury or death of a person. For the purposes of HACCP Plan development, hazards are grouped into three categories:

- biological
- chemical
- physical

Biological hazards

These are living organisms that may cause food-borne illness if they or their products (e.g. toxins) are ingested. Biological hazards are caused by bacteria, viruses, parasites or fungi. These organisms can be present in raw materials, or can be introduced through cross-contamination.

Chemical hazards

These are unwanted or incorrectly used chemicals in food that can cause poisoning when the product is consumed. Chemical hazards can also be allergens that cause allergic reactions in sensitive individuals.

Physical hazards

These are objects found in food that can cause injury to the consumer.

Biological hazards

Pathogenic bacteria

Pathogenic bacteria can cause food-borne illness. They can survive and multiply in food, often without causing spoilage. Food-borne illness can occur when people consume foods that contain pathogenic bacteria. Examples of bacteria that cause food-borne illness include:

- *Salmonella* spp.
- *Campylobacter jejuni*
- *Escherichia coli* O157:H7
- *Listeria monocytogenes*

Certain types of bacteria have the ability to produce harmful toxins that can lead to serious illness or even death when ingested. These toxins are usually present in or on the food before it is eaten. Examples of bacteria that produce toxins include:

- *Staphylococcus aureus*
- *Clostridium botulinum*

Certain types of bacteria can form spores that are very resistant to heat and chemicals, and able to withstand treatments commonly used to kill pathogenic bacteria. In the spore form, the pathogen is dormant and not harmful. However, if the environmental conditions are correct, spores can yield viable bacteria. Examples of bacteria that generate spores include:

- *Bacillus cereus*
- *Clostridium botulinum*
- *Clostridium perfringens*

Table 1 lists some common pathogens and factors that influence their growth. When the temperature or pH is outside the listed range, the pathogen is unlikely to grow. Pathogens also have a minimum a_w (water activity) below which they will not grow. The use of a_w to control bacterial growth is common in dried products such as jerky. Consider these factors when developing your HACCP Plan as they may be necessary to control pathogens.

Table 1: Examples of biological hazards and conditions to limit their growth.

Pathogen	Temperature range for growth	pH range for growth	Minimum a_w (using salt)
Bacillus cereus	5 – 55°C	4.3 – 9.3	0.912
Campylobacter jejuni	25 – 45°C	4.9 – 9.5	0.987
Clostridium botulinum type A, B and F (proteolytic)	Min: 10°C Optimum: 35-40°C	4.6 – 9	0.935
Clostridium botulinum type B, E and F (nonproteolytic)	Min: 3°C Optimum: 18-25°C	5 – 9	0.97
Clostridium perfringens	10 – 52°C	5 – 9	0.93
Pathogenic strains of *Escherichia coli*	10 – 44.5°C	3.64 – 9	0.95
Listeria monocytogenes	-0.4 – 50°C	4.4 – 9.6	0.92
Salmonella spp.	5 – 47°C	3.7 – 9.6	0.93
Shigella spp.	6.1 – 47°C	4.8 – 9.3	0.96
Staphylococcus aureus Toxin	7 – 50°C 10 – 48°C	4 – 10 4 – 9.8	0.83 0.85
Vibrio cholerae	10 – 45°C	5 – 10	0.97
Vibrio parahaemolyticus	5 – 45.3°C	4.8 – 11	0.94
Vibrio vulnificus	15 – 43°C	5 – 10	0.96
Yersinia enterocolitica	-1 – 40°C	4.2 – 10	0.945

Reference: This table has been created with information from the Canadian Food Inspection Agency, Reference Database for Hazard Identification, 2008-03-01.

Note: Always confirm that you are using the most current information when developing your HACCP Plan(s). The information in Table 1 is provided only as a guideline.

Viruses

A virus is an infectious agent that can multiply within a living host causing illness. Viruses do not cause food spoilage and cannot multiply in food and water. However, viruses can be present in food and water, and once consumed they can multiply in the human host resulting in potential food-borne illness. Viruses also have the ability to survive on surfaces and can be transmitted between people, surfaces and food. Examples of viruses transmitted through food include:

- Norovirus
- Hepatitis A virus
- Rotavirus

Parasites

Parasites live in or on other organisms such as animals and humans. They can infect people who eat contaminated food or water, resulting in potential food-borne illness. In these situations, people act as hosts providing nourishment and protection to the parasite. Examples include:

- *Cryptosporidium parvum*
- *Trichinella spiralis*
- *Giardia lamblia*
- *Taenia solium*

Fungi

Fungi such as mould and yeast are abundant in nature. They can cause spoilage of food products and a decrease in product shelf life. Mould and yeast can also pose food safety hazards due to their ability to produce harmful chemicals such as mycotoxins.

Mycotoxins are a type of toxin produced by fungi (i.e. moulds). Some types of moulds can make harmful chemical toxins that, when ingested, can cause serious adverse reactions. These toxins are common in agricultural commodities such as cereal grains, nuts, fruit, coffee, cocoa and spices. Mycotoxins are not destroyed by heating or freezing. Acceptable mycotoxin concentrations have been set for food and animal feeds. Control of mould growth during storage and transport, and the purchase of materials which are within the minimum required mycotoxin concentration levels, are important ways to control these natural chemicals. Examples of common mycotoxins include:

- aflatoxins: commonly affected crops include corn, peanuts, tree nuts (e.g. pistachios, walnuts) and various spices
- patulin: commonly found in fruit such as apples, peaches, grapes, apricots and their related products (e.g. juices, sauces)
- ochratoxin A: commonly found in grains (e.g. corn, barley, wheat and rye), peanuts and coffee

Chemical hazards

Food allergens

A food allergy is an adverse immune response to a food protein. The food protein triggering the allergic response is called a food allergen. The only option for people with food allergies is avoidance. Even tiny amounts of allergens can cause life-threatening anaphylactic reactions in sensitive individuals. Complete and accurate product labelling is critical. The most common food allergens are:

- eggs
- fish and crustaceans
- milk
- mustard
- peanuts
- sesame seeds
- shellfish
- soy products
- sulphites
- tree nuts (e.g. almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts)
- wheat

Naturally occurring chemicals

Naturally occurring chemicals often come from sources such as plants, animals or micro-organisms. These naturally occurring chemicals are generally components of food and not the result of direct contamination. For example:

- ciguatera poisoning
- mushroom toxins
- scombrotoxin

Accidentally added chemicals

Accidentally added chemicals contaminate food unintentionally. They might contaminate incoming materials before they reach the facility, or contaminate the food, ingredients or packaging materials at the facility. These chemicals may have a role in the food chain, but are not intended to be a component of the food. For example:

- cleaning chemicals
- lubricants
- paints
- pest control chemicals
- water treatment chemicals (e.g. boiler water chemicals)

Intentionally added chemicals

Intentionally added chemicals are added to food for a legitimate purpose at some point along the food chain. These chemicals may be considered safe at established levels, but are dangerous above these levels. They may become a hazard if used incorrectly or at unsafe concentrations.

For example, a meat processor may add nitrite to meat as part of a cure unit to preserve the meat by inhibiting the growth of micro-organisms. However, nitrites can be toxic in large doses and processors must ensure they do not add more than the allowable limit to their product i.e. nitrite is limited to 200 ppm in cooked meat products and 120 ppm in bacon. Examples of intentionally added chemical include:

- antibiotics
- colour additives
- flavour enhancers
- fungicides
- pesticides
- preservatives (e.g. nitrites)
- vitamins and minerals

Physical hazards

Physical hazards are foreign materials in food that may cause injury. For example:

- extraneous items directly related to your product or process (i.e. walnut shells, corn stock, bones, cherry pits)
- glass
- jewellery
- metal
- paint chips
- pens/pencils/paper clips
- plastic
- stone
- wood

Grouping Products for HACCP Plans

To start developing your HACCP Plans, determine how many HACCP Plans you need. The number of HACCP Plans needed is unique to your facility, products and processes. This section provides guidance on how to group products for the purpose of developing HACCP Plans.

The number of HACCP Plans needed depends on:

- the types of products processed
- the number of products processed
- the differences in processing steps
- the differences in equipment used to process the products
- the hazards and controls associated with the ingredients and products

A separate HACCP Plan is not necessary for each product.

Products can often be grouped into categories, with one HACCP Plan created for each category. This grouping helps reduce the amount of paperwork required for HACCP Plans. Products can be grouped together if they differ only in characteristics that do not affect food safety (e.g. the type of seasoning used – hot vs. mild).

If you process similar products through the same processing methods, and the end products have the same hazards, you will likely group these into one HACCP Plan. But if you process different products, or products that have different food safety hazards associated with the processing steps or end product, these products will be grouped into separate HACCP Plans.

For example, if you process five different flavours of cooked meatloaf, they can all be grouped in one HACCP Plan. If you process cooked meatloaf, dry cured pepperoni and raw boneless chicken breast, you will need three separate HACCP Plans. Some examples of grouping are:

- a Quiche HACCP Plan could include mushroom quiche and broccoli quiche
- an Ice Cream HACCP Plan could include vanilla ice cream, chocolate ice cream and strawberry ice cream
- a Minimally Processed Vegetable HACCP Plan could include peas and carrots
- a Cooked Sausage HACCP Plan could include hot dogs, mild spice sausage and extra spicy sausage

Determining how to group products for HACCP Plans

As a starting point for determining which products to group together:

1. Make a list of all of the products you process.
2. Consider the following.
   - The processes and equipment used to process each product. Start by grouping products with similar processing steps.
   - Any specific final product characteristics (e.g. cooked, pH, pasteurized) necessary for food safety. Group products with the same process techniques required to achieve these characteristics.
   - For each group, think about the ingredients used. If products have similar ingredients with similar hazards, they may be grouped together. However, if products have ingredients with significantly different hazards, consider whether these products need to be in separate plans.
   - The flow of product through your facility during processing. Are there products that follow significantly different paths that should be grouped separately?

You might need more than one attempt at grouping your products. Once you begin the process of developing your HACCP Plans, you may see similarities or differences in your products/processes you had previously overlooked, which may lead you to reassess product groupings.

For each group of products (i.e. each HACCP Plan) develop a name to accurately reflect the category of product. For example "Quiche HACCP Plan" (could include mushroom quiche and broccoli quiche). This name will be included at the top of each of the eight HACCP forms, in the section for "Plan name."

HACCP Documentation and Records

HACCP documents and records fall into three categories. All documents and records must be kept up-to-date and be available during an audit.

Development documents

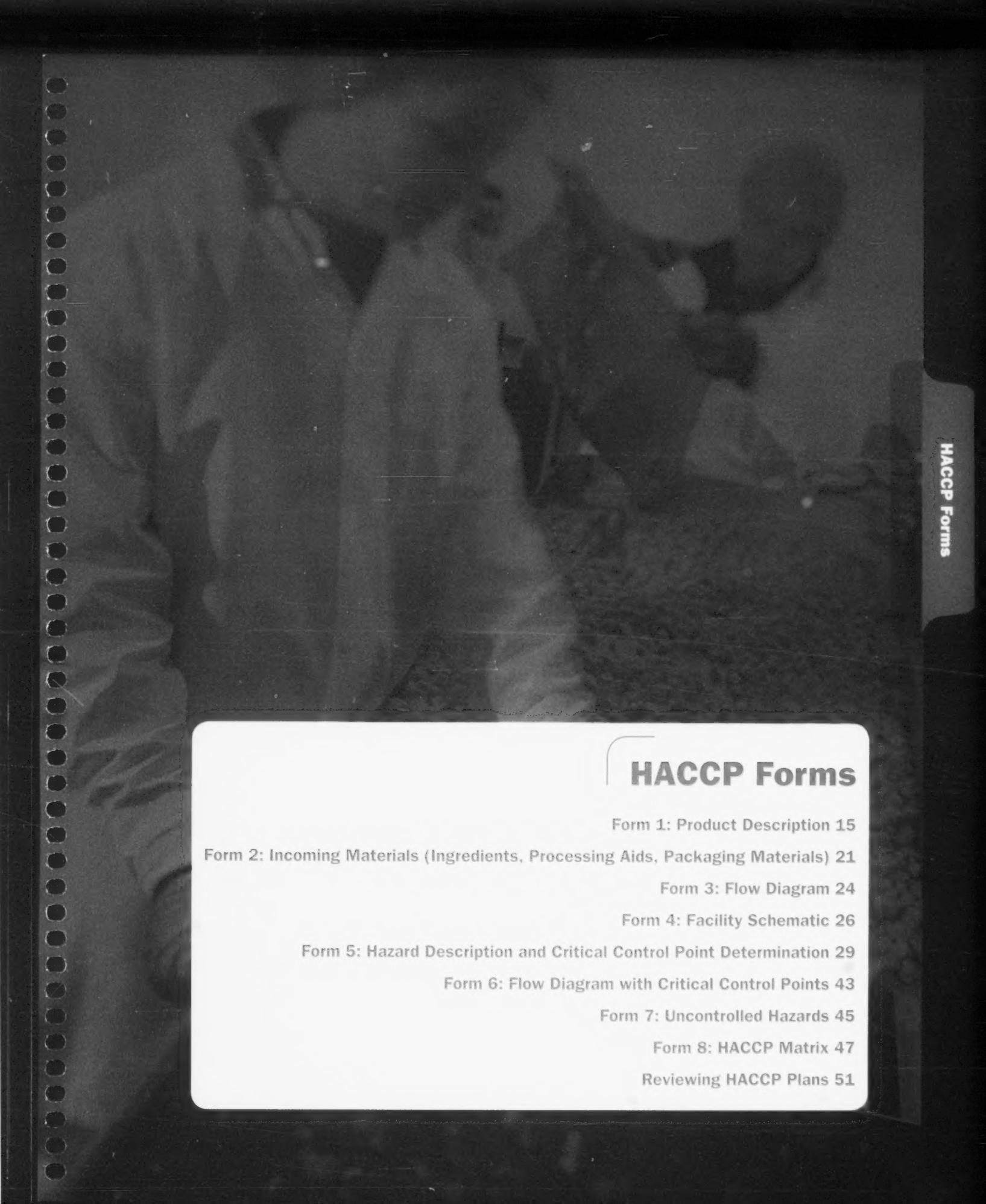
These are the documents used to develop your HACCP Plan(s) and support your decision making processes (e.g. *Advantage HACCP* Forms 1-8). These documents are generally completed once during development, and only changed when modifications to the HACCP Plan(s) are required.

Operational records

These are the checklists/records used to monitor and verify Critical Control Points (e.g. recording actual temperature, pH, metal detector results). These records are used on a day-to-day basis to log results and demonstrate that HACCP Plan activities are being carried out in the facility as specified in the written HACCP Plan(s).

Log book

The log book is used to summarize any changes made to the HACCP Plans. Each entry in the log book should include the date the change was made, the nature of the change, the reason for the change, and who made the change. The same log book used for the GMPs can be used for the HACCP Plans.



HACCP Forms

HACCP Forms

Form 1: Product Description

Purpose

To describe the product(s) being processed.

Importance

Product characteristics, ingredients and intended use can be used to help identify potential food safety hazards.

How to complete Form 1

At the top of Form 1, record the HACCP Plan name. The HACCP Plan name applies to all products grouped into this particular plan, commonly referred to as the "category" of products being processed. For more information on grouping products, refer to Grouping Products for HACCP Plans on page 12.

Note: Use one row of the form for each product in the HACCP Plan.

Column 1: Product name

Write the name of each product (exactly as shown on the product label) included in this HACCP Plan. Use one row for each product name. Every HACCP Plan is different and the number of product names depends on the number of products processed by the individual company. There may only be one or two products included in the HACCP Plan, or there may be numerous products.

For example, if a facility makes only one variety of sausage, the name of the sausage product is written in the first row. However, if a facility makes 20 different varieties of sausage (e.g. hot, medium, mild spice, etc.), all 20 sausage product names are listed on this form, using 20 different rows.

This form must list each product name as it appears on the product label. If there is one sausage variety sold under three brand names, the form must reflect this. In this case, it may be easiest to use one row to list the sausage variety and include in brackets each of the brand names it is sold under. For example: "Spicy Sausage (sold as "Fred's Spicy Sausage", "Best Brand Spicy Sausage" and "Classic Spicy Sausage").

It is important to include every product processed in the facility, even if there are many similar products. This ensures each individual product is considered, and potential hazards associated with one product are not overlooked throughout the HACCP Plan.

For each product listed in the "Product name" column, complete all other columns on the form.

Column 2: Product type

Write a description of the finished product as it pertains to food safety for the consumer or user. For example, the description could be "raw" if a facility processes a raw sausage product, or "ready-to-eat" for a cooked product.

Product type is important for determining the product's shelf life and storage conditions. It is also important for the customer to know if a product is ready-to-eat, or must be cooked prior to consumption. This information may also be important when considering potential sources of cross-contamination. For example, if a ready-to-eat meat product is processed, it is crucial to ensure there is no cross-contamination of the finished ready-to-eat product from incoming raw meat.

Column 3: Product characteristics important for food safety

Record any product characteristics that could affect food safety. It is important to understand what characteristics of the products are critical for ensuring food safety. Examples of important product characteristics include:

- pH: a measure of the acidity or alkalinity of a substance
- water activity (a_w): a measure of the availability of water in food for bacterial growth
- salinity: a measure of the salt content of food

If a product must achieve a specific product characteristic in order to ensure food safety, this needs to be considered in the HACCP Plan. Product characteristics such as pH, a_w and salinity are often used to inhibit/prevent the growth of pathogens. It is very important that these parameters are carefully controlled. Failure to control these parameters could result in pathogen growth or survival, or decreases in product shelf life.

Column 4: Does finished product and recipe meet the requirements of the Food and Drugs Act and Regulations?

Answer "yes" or "no" to this question. All food products sold in Canada are subject to the *Food and Drugs Act* and Regulations. You must ensure your products comply with this Act and Regulations. The *Food and Drugs Act* and Regulations include requirements for items such as Food Additives (Part B, Division 16), Food Packaging Material (Part B, Division 23), Meat Preparation and Products (Part B, Division 14), Nutritional Labelling, Addition of Vitamins, Mineral Nutrients or Amino Acids To Foods (Part D, Division 3), etc. To ensure you are in compliance with this Act and Regulations, you must be familiar with your products, ingredients and processes. Review any applicable sections of the Act and Regulations to determine that you are in compliance. Once you have confirmed your finished product and recipe meet the requirements of the Act and Regulations, record "yes" in this column.

If you are not in compliance, you must make the necessary changes to your product, recipe, process, etc. to ensure you are in compliance. Do not proceed with processing until you are in compliance with the *Food and Drugs Act* and Regulations.

Column 5: Does label meet requirements of the Consumer Packaging and Labelling Act and Regulations?

Answer "yes" or "no" to this question. Food products sold in Canada are subject to the *Consumer Packaging and Labelling Act* and Regulations. This Act and Regulations include requirements for items such as appropriate units of measurement, declaring net quantity, allergen declaration, bilingual label requirements, etc. Ensure your product packaging and labels meet the requirements of the *Consumer Packaging and Labelling Act* and Regulations. Review any applicable sections of the Act and Regulations to determine that you are in compliance. Once you have confirmed that your product packaging/labels meet the requirements of the Act, record "yes" in this column.

If you are not in compliance, you must make the necessary changes to your packaging/labels to ensure you are in compliance. Do not proceed with processing until you are in compliance with the *Consumer Packaging and Labelling Act* and Regulations.

Column 6: Does product contain restricted ingredients as per Food and Drugs Act and Regulations?

Answer "yes" or "no" to this question. Your product may contain ingredients whose uses are restricted in Canada. Review the *Food and Drugs Act* and Regulations for restricted ingredients and maximum allowable concentrations that pertain to your product. Ensure any restricted ingredients used to process your product are recorded in this column, and that they are used correctly. Examples of restricted ingredients include food additives such as ascorbic acid, caffeine, aspartame, sodium nitrate, etc.

If you are not in compliance, you must make the necessary changes to the use of restricted ingredients to ensure you are in compliance. Do not proceed with processing until you are in compliance with the *Food and Drugs Act* and Regulations.

Note: If you are selling product outside the country, check the appropriate legislation to determine acceptable restricted ingredients and allowable limits. Permitted ingredients and maximum allowable concentrations may vary depending on the country.

Column 7: Does product contain allergens as per Health Canada Guidelines?

Answer "yes" or "no" to this question. Some of your products may contain allergenic ingredients. Health Canada and the Canadian Food Inspection Agency (CFIA) have identified 11 important allergens to look for – eggs, fish and crustaceans, milk, mustard, peanuts, sesame seeds, shellfish, soy products, sulphites, tree nuts and wheat.

Evaluate all ingredients used in your products for allergens. If you use an ingredient composed of several different ingredients, you must assess each individual ingredient to determine if that ingredient contains an allergen.

For example, consider a facility processing a product containing chocolate as an ingredient. Chocolate by itself is not identified as a potential allergen. However, the ingredients in chocolate (e.g. sugar, milk, cocoa butter, chocolate liquor, soy lecithin and vanillin) contain two types of allergens – milk and soy.

For this reason, it is very important to carefully review all ingredients used to make your product. Once you have done this, record any allergens included in your product in this column. Ask your supplier to provide and guarantee the components of each ingredient.

If you process some products that contain allergens, and some products that don't – or if products you process contain different allergens – consider using a precautionary statement. Precautionary statements warn consumers of the possible inadvertent presence of a food allergen. Currently, there is no prescribed wording for precautionary declarations. However, the CFIA recommends the following options: "may contain X" or "not suitable for consumption by persons allergic to X", where "X" is the name of the allergen.

Use precautionary statements when a product may have inadvertently come into contact with a food allergen, or there is a potential for cross-contamination. Precautionary statements can't be used when the allergen is present in the food as an ingredient. And precautionary statements can't be used as a replacement for an allergen control program.

Other countries may consider additional or different products as allergens. Depending where you sell your product, you must identify other allergens on your label according to the law in that particular country.

Column 8: Shelf life of product

Record the shelf life of each product in the HACCP Plan. This will depend on the product e.g. one week, 30 days, six months, etc. You must also record the conditions required to achieve this shelf life. For example, seven days at 4°C, or six months at room temperature. This is most important for products with a shelf life impacted by the storage conditions, and where the shelf life would be decreased if the necessary storage requirements are not maintained.

It is important to realize there are many variables that can affect product shelf life such as changes in product ingredients, new ingredient suppliers, changes in process, etc. If you do not know the shelf life of your product, shelf life testing and determination are required, and can be done by an outside laboratory or in-house with the appropriate materials and expertise.

Be aware of any process or ingredient changes that may impact product shelf life.

Column 9: Storage and distribution instructions

Record any storage or distribution instructions necessary to maintain food safety. The shelf life of the product may depend on how the consumer or user stores the product, so ensure storage instructions are clear and include any special conditions including temperature or humidity requirements. For example, a refrigerated product would require "Keep refrigerated" instructions on the packaging/label. Other examples may include "Keep refrigerated after opening", "Keep frozen prior to use", etc.

Column 10: Intended use of the product

Record the intended use of the product and the intended consumer/recipient of the product.

Include a short description of how the intended recipient of the product should use it. For example, record "cook to an internal temperature of X°C" if consumers need to cook the product prior to consumption, or record "for further processing" if the product is intended to be further processed at another facility.

Also include a short description of the intended consumers. For example, if the product is intended for the general public, record "retail sale for general public" in this column. If the product is intended for consumers with weakened or impaired immune systems including the elderly, infants and other immuno-compromised individuals (e.g. cancer patients, etc.), then this information is recorded here. For example, you could record "wholesale distribution to nursing homes/hospitals/daycares for immuno-compromised individuals". This information is important to identify as extra precautions may be necessary when processing, handling, storing, transporting and preparing products for these particular consumer groups.

For specific Acts and Regulations please consult the Department of Justice Canada: Justice Laws Web Site at: *http://laws.justice.gc.ca/en/*

- *Food and Drugs Act*
- Food and Drug Regulation
- *Consumer Packaging and Labelling Act*
- Consumer Packaging and Labelling Regulation

Figure 2. Sample Form 1

Form 1: Product Description

Plan name: **Cooked Sausage Products**

Write the plan name that describes all products in Column 1 grouped together in this HACCP Plan.

Write the name of each product in this HACCP Plan. Use one row for each individual product.

List any product characteristics that have an impact on food safety, and must be controlled.

Determine if the product packaging/label is in compliance with the *Consumer Packaging and Labelling Act* and Regulations.

Determine if the product contains any allergens. List all allergens present in the product.

List all storage and distribution instructions required to maintain food safety.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10
Product name	**Product type** *(e.g. cooked, raw, processed, ready to eat)*	**Product characteristics important for food safety** *(e.g. pH, a_w, salinity, other qualities)*	**Does finished product and recipe meet the requirements of *Food and Drugs Act* and Regulations (Y/N)?**	**Does label meet the requirements of *Consumer Packaging and Labelling Act* and Regulations (Y/N)?**	**Does product contain restricted ingredients as per *Food and Drugs Act* and Regulations (Y/N)?** *If "yes", list restricted ingredients.*	**Does product contain allergens as per Health Canada Guidelines (Y/N)?** *If "yes", list allergens.*	**Shelf life of product**	**Storage and distribution instructions** *(e.g. keep refrigerated, keep frozen, humidity control).*	**Intended use of the product** *(e.g. for general public, elderly, immuno-compromised, infants, further processing).*
ABC Brand Hot Dogs	Fully cooked, not shelf stable	NA	Yes	Yes	Yes • sodium nitrite • sodium erythorbate	Yes • soy	21 days at 4°C	Keep refrigerated	Retail sale for general public

Describe the finished product. What type of product reaches the user or customer?

Determine if the product is in compliance with the requirements of the *Food and Drugs Act* and Regulations.

Check the product formula. Does it contain any restricted ingredients as per the *Food and Drugs Act* and Regulations? List these ingredients.

List the shelf life of the product. State the storage conditions required to achieve this shelf life.

List the intended use of the product and the intended recipient.

Form 2: Incoming Materials (Ingredients, Processing Aids, Packaging Materials)

Purpose

To identify all ingredients, processing aids and packaging materials used to process the product(s), or that come in contact with the product(s) listed on Form 1.

Importance

If any incoming materials are not listed on this form, potential hazards associated with these materials will not be considered in the HACCP Plan and could lead to a situation where a food safety hazard is overlooked and food safety may be compromised.

Some examples of how incomplete lists on Form 2 could lead to food safety hazards include:

- if an ingredient that is an allergen is not listed, the HACCP Plan will not include specific labelling procedures to alert the consumer to this hazard
- if an ingredient that may contain pathogenic bacteria is not listed, adequate cooking temperatures may not be achieved
- if a processing aid that must be used within certain limits is not listed, maximum limits may be exceeded
- if a packaging material that is not food grade is not listed, this item will not be analyzed and unsafe chemicals may migrate from the packaging into the food product

How to complete Form 2

At the top of Form 2, record the HACCP Plan name.

Column 1: List all ingredients

List ingredients and subcomponents of ingredients. All ingredients required to process each of the products listed on Form 1 must be listed. List each ingredient individually by product name, rather than by category or type, for example, list apple, kiwi, pear – not just fruit. If you have more that one product listed on Form 1 – and some products include the same ingredients – just list each ingredient once on this form. If you use an ingredient that is composed of several different ingredients, list each component ingredient to determine allergens. List the components by using brackets next to the main ingredient name, for example "milk chocolate (sugar, cocoa butter, non-fat dry milk, soy lecithin, salt, artificial flavour)." Make sure your ingredient list is complete, and be sure ingredients listed are the same as those listed on your packaging/labels.

Column 2: List all processing aids

List all the processing aids used to process each of the products listed on Form 1. Processing aids are substances added to a food, or used to process a food, that are not present in the finished product or present at insignificant and non-functional levels. For example, washing and peeling agents, or headspace flushing gases in modified atmosphere packaging.

Column 3: List all packaging materials

List all the packaging materials required for each product listed on Form 1. The list of packaging materials includes primary, secondary and tertiary packaging. Primary packaging comes into direct contact with the food item. Secondary packaging surrounds the primary packaging, and tertiary packaging surrounds the secondary packaging. Secondary and tertiary packaging does not touch the food product, e.g. pre-printed retail box, shipping carton, etc. If ink is used for labelling/coding, list it here.

Note: The lists on Form 2 are limited to items required in the processing facility to actually process the products. Do not include other items such as maintenance chemicals, office supplies (e.g. pens, paper), clothing (e.g. hair nets, lab coats), etc.

Figure 3. Sample Form 2

Form 2: Incoming Materials (Ingredients, Processing Aids, Packaging Materials)

Plan name: **Cooked Sausage Products**

Write the plan name that describes all products grouped together in this HACCP Plan.

List all incoming ingredients, processing aids and packaging materials.

Column 1	Column 2	Column 3
List all ingredients	**List all processing aids**	**List all packaging materials** *(primary, secondary, tertiary, etc.)*
Raw ground beef	Wood chips	Polyethylene bags – primary
Ice	Municipal (city) water	Cardboard box – secondary
Salt		Tape
Dextrose		Labels
Soy protein		Ink
Extra fine spice mix (black pepper, oregano, garlic, cardamom, wheat flour)		
Sodium nitrite		
Natural casing		

In this column, list all the ingredients required to process the products listed on Form 1.

Each ingredient must be listed individually, rather than groups or types of ingredients being listed.

In this column, list all the processing aids required to process the products listed on Form 1.

In this column, list all the packaging materials required for each of the products listed on Form 1.

This includes primary, secondary and tertiary packaging.

Form 3: Flow Diagram

Purpose

To show the process steps for the products listed on Form 1 and the relationship between each process step.

Importance

Show each process step so potential hazards at each step can be identified (on Form 5b) and controlled. If an incomplete flow diagram is developed, uncontrolled hazards associated with the missing process steps may result in food safety issues.

How to complete Form 3

At the top of Form 3, record the HACCP Plan name.

The process flow diagram allows all the processing steps to been seen at a glance. The flow diagram is used to illustrate:

- each process step required to process the products listed on Form 1 (e.g. receiving, storage, mixing, grinding, shipping, etc.)
- the relationship between the process steps (e.g. the order in which the steps are performed)

To create a flow diagram, follow these steps.

1. Determine the number of process steps.
2. Draw enough rectangles for each process step – these are generally drawn vertically down the page.
3. List one process step in each rectangle.
4. Number each rectangle.
5. Use arrows, where applicable, to connect or link process steps.

The example on the next page shows a completed flow diagram.

Note: If the products on Form 1 follow the same basic flow, but have minor variations in processing steps, this can be shown on one flow diagram (at right). A separate flow diagram does not need to be created to reflect minor variations on the main process.

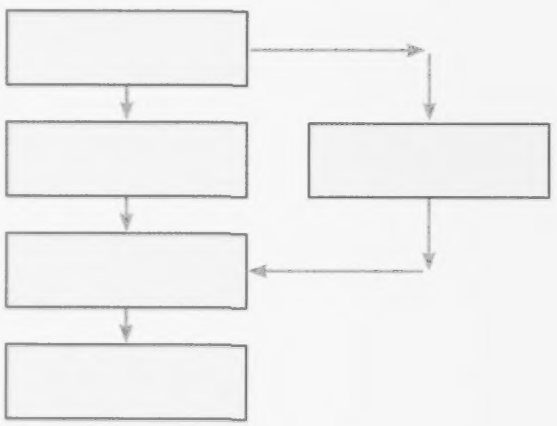
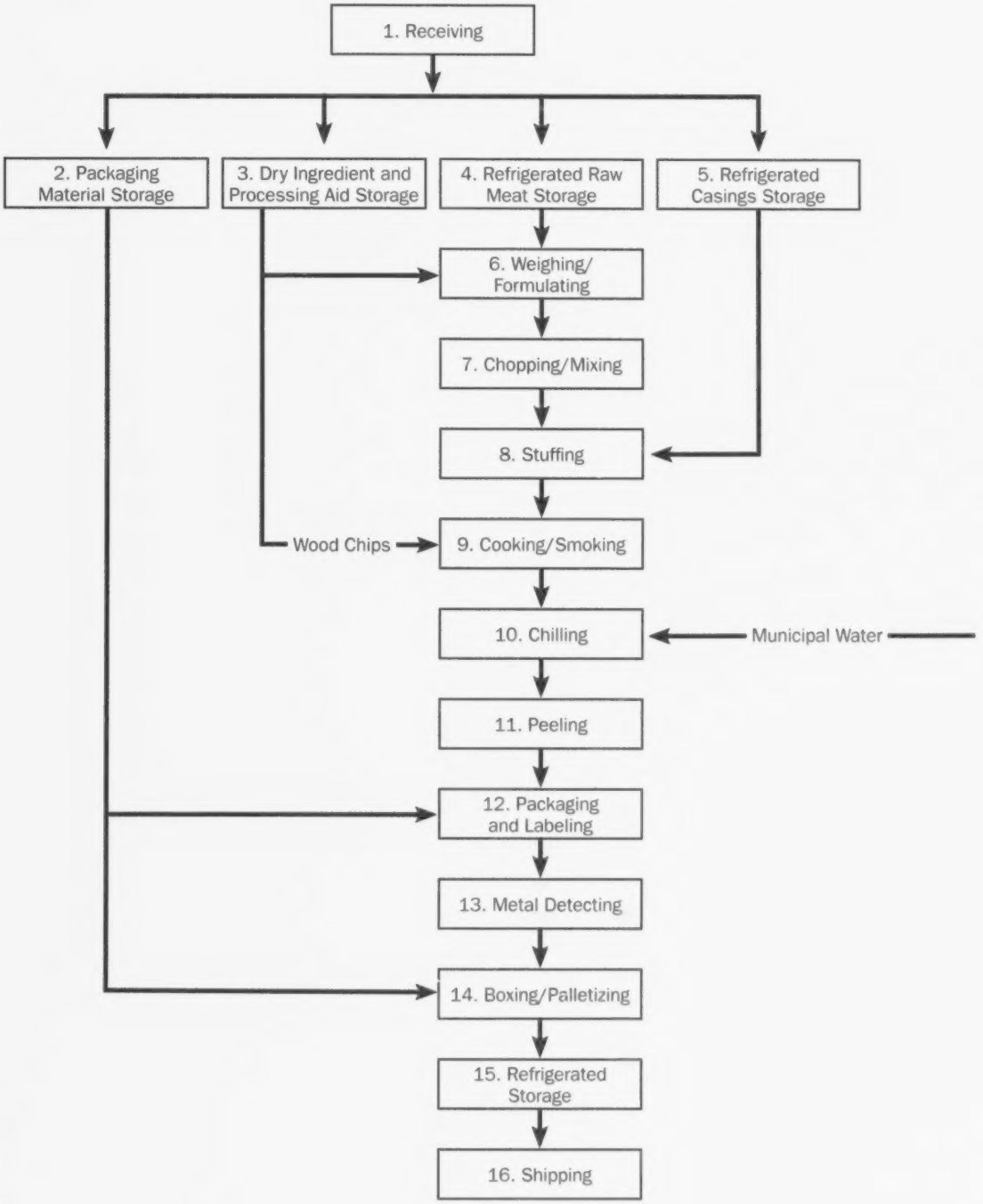


Figure 4. Sample Form 3

Form 3: Flow Diagram

Plan name: **Cooked Sausage Products**

Write the plan name that describes all products grouped together in this HACCP Plan.



Form 4: Facility Schematic

Purpose

To show the movement of people, products and materials (e.g. raw product, finished product, ingredients, packaging materials, employees, waste, chemicals and allergens) through the facility with respect to the location of equipment and the relative amount of space.

To identify potential points of cross-contamination.

> Cross-contamination is the physical movement or transfer of harmful micro-organisms, allergens, chemical contaminants or any foreign substances, from one person, object, food or place to another.

Importance

The facility schematic allows for the identification of potential sources of biological, chemical or physical cross-contamination. The facility schematic shows the movement of people, products and materials through the facility, and the location where process steps occur within the physical facility.

A facility will have more than one HACCP Plan if there are different product types, so consider all activities occurring within the facility and not just those associated with one HACCP Plan. For example, a facility may have a HACCP Plan for a product that does not have any allergens. The facility may also have other HACCP Plans for products with allergens. In this case, it is very important to consider those allergens and how they move through the facility. In order to identify every potential point of cross contamination, it is crucial to consider all product, people and material flows occurring in the facility.

> Develop Form 4 for all the products processed in the facility, not just the products from a single HACCP Plan to ensure all potential points of cross-contamination are identified.

Depending on your process and facility, it may be challenging to represent all flows on one piece of letter-sized paper. Consider using larger paper (e.g. blueprint size) or acetates that can be laid on top of each other.

How to complete Form 4

At the top of Form 4, record the HACCP Plan name.

To create a facility schematic diagram, follow these steps.

1. Draw a diagram that represents each room and area of the facility (e.g. receiving, storage, preparation, processing, packaging, shipping, washrooms/change rooms/lunchrooms). Make the diagram as close to scale as possible. If your facility has existing blueprints, these can be used.

2. Identify the name of each area/room.
3. Show all equipment in its correct location within the facility.
4. Illustrate the flow of people, products and materials through the facility using lines with arrowhead to show direction. Use different lines (e.g. colour, dash, etc.) for each category of item moving through the facility (e.g. raw product, finished product, ingredients, packaging materials, employees, waste, chemicals and allergens). Use continuous lines to show the complete path, rather than just where the path enters or leaves an area or room.
5. In places where different lines cross, or where lines are in close proximity, there is potential for cross-contamination to occur and these places must be marked. Write a B (for biological hazard), C (for chemical hazard) or P (for physical hazard) at each location where cross-contamination may occur.

Some potential points of cross-contamination include crossover between:

- raw and cooked product – biological
- allergen product and non-allergen product – chemical
- inedible materials and finished product – biological
- chemicals and ingredients/finished product/food contact surfaces – chemical
- personnel in incompatible areas – biological or chemical

Here are some examples of issues to consider.

- Is the same equipment used for non-allergen and allergen containing products?
- Do the same employees handle products with and without allergens?
- Do the same employees handle ingredients/finished product and waste?
- Is there a potential for the products flows to lead to cross-contamination?
- Are chemicals required in processing areas during processing?

For example, the sample Form 4 on page 28 includes a potential point of biological cross-contamination, identified as B3, between raw and cooked meat product outside the smokehouse. This is because raw meat entering the smokehouse could potentially contaminate cooked meat exiting the smokehouse with pathogenic bacteria. By identifying this as a potential point of cross-contamination, the facility is better able to control this hazard through operational means, e.g. separation in time between smokehouse loading and unloading operations.

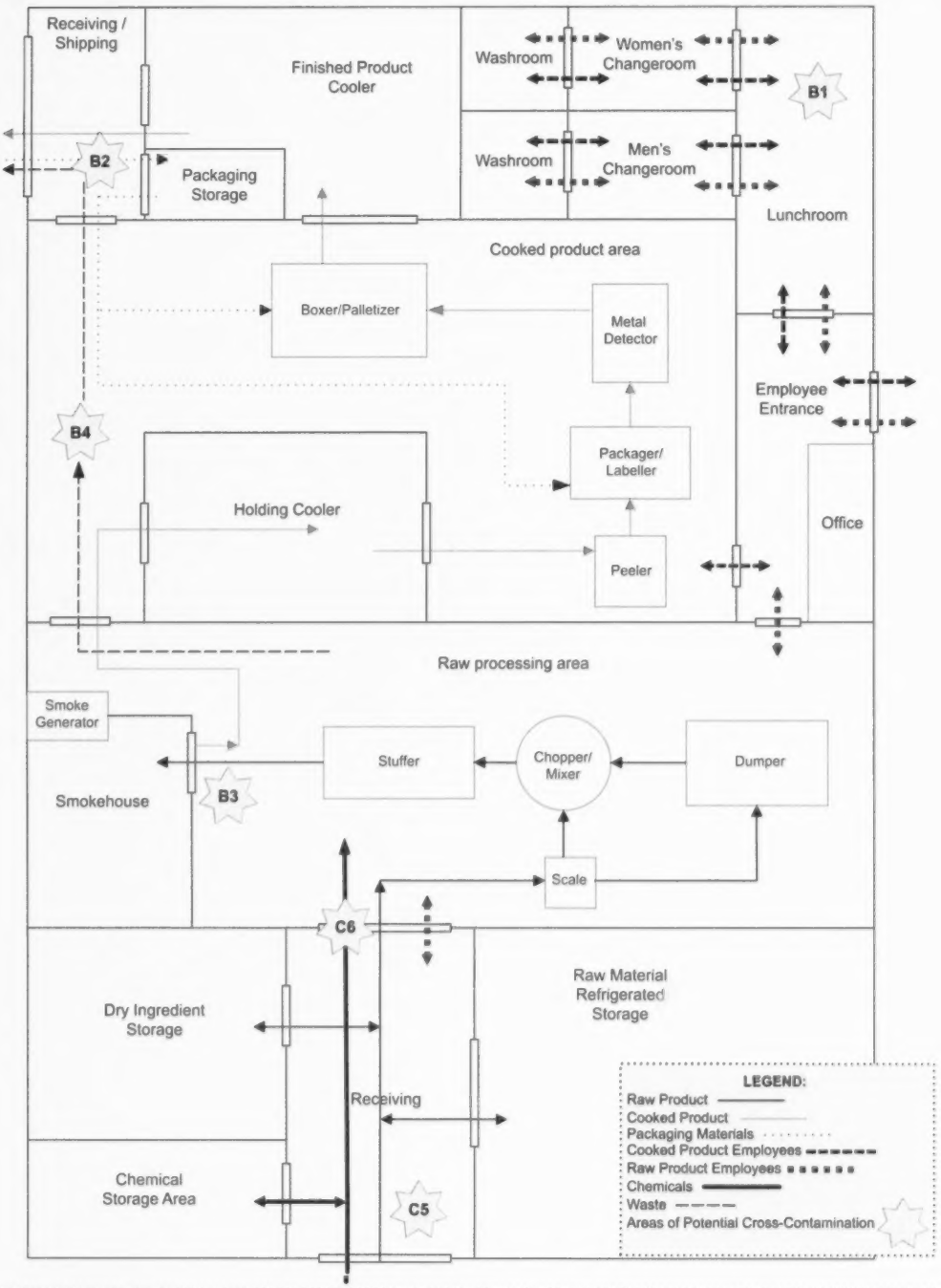
Ensure the flow diagram and facility schematic are accurate and represent what is occurring in the facility, as they are used in the hazard analysis. Verify these two documents by physically walking through the facility during operations to ensure all steps, people, flows, equipment and potential points of contamination are identified. Based on your observations during the verification walk through, change diagrams with any errors or omissions, and retrain any employees not following the proper paths or procedures.

Write the plan name that describes all products grouped together in this HACCP Plan.

Figure 5. Sample Form 4

Form 4: Facility Schematic

Plan name: **Cooked Sausage Products**



B1: Potential biological cross-contamination between employees handling raw product and employees handling cooked product.
B2: Potential biological cross-contamination between cooked product/packaging materials and waste.
B3: Potential biological cross-contamination between raw product entering the smokehouse and cooked product exiting the smokehouse.
B4: Potential biological cross-contamination between waste and employees/cooked product as waste travels through cooked product area.
C5: Potential chemical cross-contamination between chemicals and raw product.
C6: Potential chemical cross-contamination between chemicals and products in processing areas (cooked and raw).

Form 5: Hazard Description and Critical Control Point Determination

Purpose

To list and analyze the hazards associated with the:

- ingredients, processing aids and packaging materials identified on Form 2 – Incoming Materials
- process steps identified on Form 3 – Flow Diagram
- potential points of cross-contamination identified on Form 4 – Facility Schematic

To determine which hazards must be controlled at a Critical Control Point (CCP).

To determine which steps are CCPs.

> **CCP = Critical Control Point**
> A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. (Codex definition)

A CCP is a step in your process that is absolutely necessary to control food safety. It is a step in the process where you must have control over a food safety hazard. Sometimes it is possible to completely prevent or eliminate a hazard, in other cases the hazard can only be reduced to an acceptable level.

Importance

If an incomplete list of hazards is developed, missed hazards will not be analyzed or controlled in the HACCP Plan and may result in food safety issues. Hazards that are not properly analyzed may not be properly controlled.

Forms 1 to 4 are used to collect information about your product and process. This form is used to analyze that information.

How to complete Form 5

Form 5 uses a "decision tree" to assist in determining which hazards are controlled by a CCP. A decision tree is a series of questions completed in sequence to lead to a decision.

Form 5 is presented in two parts.

- **Form 5a** – used for Incoming Materials from Form 2 (i.e. ingredients, processing aids and packaging materials) and Potential Points of Cross-contamination from Form 4.
- **Form 5b** – used for Process Steps from Form 3.

The questions on Form 5a and Form 5b are very similar, but not identical. They are designed to reflect the difference between assessing hazards with incoming materials and potential points of cross-contamination, versus assessing hazards with processing steps. Form 5a has five columns, Form 5b has eight columns.

Form 5a Explanation

Form 5a: Hazard Description and Control Incoming Materials and Potential Points of Cross-Contamination

Plan name: _____

Column 1	Column 2	Column 3	Column 4	Column 5
List all: • **incoming ingredients and materials (copy these from Form 2)** • **potential points of cross-contamination (as shown on Form 4)**	**List all biological, chemical and physical hazards associated with:** • **each incoming ingredient and material listed in column 1** • **each potential point of cross-contamination listed in column 1**	**Q1. Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?** **Answer "yes" or "no".** *If "yes", list the GMP program that controls the hazard. Stop. Continue with next hazard.* *If "no", continue to column 4.*	**Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?** **Answer "yes" or "no".** *If "yes", continue to column 5.* *If "no", stop. Continue with the next hazard.*	**Q3. Could a control measure be used to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", list the control measure and ensure the control measure is included in your process, and is identified in Form 5b.* *If "no", list the hazard on Form 7.*

At the top of Form 5a, record the HACCP Plan name.

Column 1: List all incoming ingredients and materials (copy these from Form 2), and potential points of cross-contamination (as shown on Form 4).

List:

- each ingredient, processing aid and packaging material listed on Form 2
- each potential point of cross-contamination shown on Form 4

Copy this information from Form 2 and Form 4, and use one row of Form 5a for each item.

Column 2: List all biological, chemical and physical hazards associated with each incoming ingredient and material listed in column 1, and with each potential point of cross-contamination listed in column 1.

For each item listed in column 1, use column 2 to list:

- potential biological hazards – e.g. presence and growth of pathogenic bacteria (e.g. *Escherichia coli, Listeria monocytogenes*)
- potential chemical hazards – e.g. pesticide residues, presence of allergens, non food-grade packaging
- potential physical hazards – e.g. presence of metallic foreign materials, presence of bone fragments

It is possible for each ingredient, processing aid, packaging material and potential point of cross-contamination to have more than one hazard associated with it. In this case, it may be helpful to sub-divide each row using dashed lines. Describe each identified hazard separately – this will help manage the flow of information through the form (see the Sample Form 5a on page 35).

Determining the hazards associated with incoming materials is one of the more difficult aspects of developing a HACCP Plan. It may be possible to determine significant hazards based on knowledge, judgement and experience, or using historical data. There may be cases where it is necessary to use a more formal approach – determining the hazards associated with each process step may require research or external scientific expertise.

To determine the potential biological, chemical and physical hazards, consider consulting one or more of the following resources:

- CFIA Reference Database for Hazard Identification (lists hazards associated with a number of ingredients, processing aids, packaging materials and process steps)
- reference texts
- the latest scientific literature
- historical and known hazards associated with specific incoming materials
- relevant Codes of Practice
- regulatory requirements or recognized guidelines
- expert determination (e.g. academia, government, industry experts)
- generic models
- food safety consultants
- food processor organizations
- information from suppliers (e.g. product specification, certificate of analysis)

When listing each hazard, provide a brief description to explain the hazard and where needed, the potential source. This information will be important when considering control measures to address the hazards.

For example, for an incoming ingredient include detail such as "presence of pathogenic bacteria, e.g. *Listeria monocytogenes, Escherichia coli*" as a potential hazard, rather than just "bacteria".

Review the Sample Form 5a on page 35 to see examples of how hazards can be described.

Column 3: Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?

This column requires a "yes" or "no" answer. To answer this question, determine if there is a Good Manufacturing Practices (GMP) program to control the hazard listed in column 2.

If there is a GMP program that controls the hazard, record "yes" and list the specific GMP (e.g. P1.1 Personnel Practices). In this case, you don't need to go any further on this form for this hazard once you have listed the GMP – proceed to the next identified hazard. If there is no GMP program capable of controlling the hazard, answer "no" and proceed to column 4.

To answer this question, it is important to understand what is meant by "to a level that will prevent it from compromising the safety of the finished product." Consider the type or level of control that a GMP can provide. In some cases, there may be a GMP that provides partial control over a hazard but does not fully control a hazard. In other cases, the GMP program will fully control the hazard.

For example, consider an incoming ingredient that is an allergen. Although storage and transport of allergens are addressed in GMPs, there is no GMP program that fully controls proper labelling of allergens on finished product packaging. So if a facility has allergens, Forms 5a and 5b must be completed to determine how to ensure all allergens are properly labelled on all products.

On the other hand, consider an incoming packaging material that could pose a chemical hazard if it's not food grade. This hazard is completely controlled by the Receiving GMP program and the rest of Form 5a doesn't need to be completed for this hazard – simply state the GMP program you are relying on.

Column 4: Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

This column requires a "yes" or "no" answer. To answer this question, determine and understand what the acceptable levels are. To determine acceptable levels, consult regulatory requirements or industry best practices. If there are no established acceptable levels, it is your responsibility to justify to the auditor, during the certification process, how and why you arrived at your answer.

To determine acceptable levels, consider the impact certain levels of the hazard could cause. There may be certain levels of a hazard that do not cause illness or injury, but above those levels the hazard can cause harm. In this situation, consider seeking external expert advice (e.g. food safety consultant, academia).

When answering this question, consider the historical compliance of the hazard being analyzed. Have repeated results of micro testing indicated the presence of a pathogen in an incoming ingredient? Have you or your suppliers had to perform a recall due to the hazard?

If your answer is "no", be sure information to justify this decision is available. For example, monthly micro test results performed on an ingredient for the past two years that indicate there has not been contamination with a specific pathogen. You may need several pieces of scientific evidence supported by laboratory results to thoroughly support your claim.

Consider the example of a company that receives a ready-to-eat chocolate product. The chocolate is received, melted and remoulded, then packaged and shipped. Although there is potential for a biological hazard associated with the incoming chocolate, the hazard is not likely to occur in excess of the acceptable level. So the answer in this column would be "no". In order to justify this answer, an auditor may ask for documentation to prove the statement. The company could provide the results of monthly micro tests done on the incoming chocolate and the finished product to demonstrate there is no historical incidence, as well as proof there have been no customer complaints or recalls due to this hazard.

If you answer "yes" in this column, proceed to column 5.

Column 5: Could a control measure be used to eliminate or reduce the hazard to an acceptable level?

This question is asking if there is any action or activity that can be implemented to prevent or eliminate the hazard, or reduce it to an acceptable level. Consider any control measures that currently exist as part of the process at any step and, if needed, any control measures that could reasonably be expected to be implemented. You may have to adapt your process to include a control measure not currently in use.

The question requires you to answer "yes" or "no". If the answer is "yes", you must list what the control measure is and continue to the next column. If the answer is "no", list the hazard on Form 7.

Form 7 is used to list hazards that cannot be controlled at the facility, and must be controlled elsewhere in the food chain – e.g. pesticide withdrawal times, cooking of raw ground beef by the consumer. A more detailed explanation of Form 7 is on page 45.

Figure 6 shows the questions from Form 5a in a decision tree format.

Figure 6. Decision tree to identify CCPs for incoming materials and potential points of cross-contamination

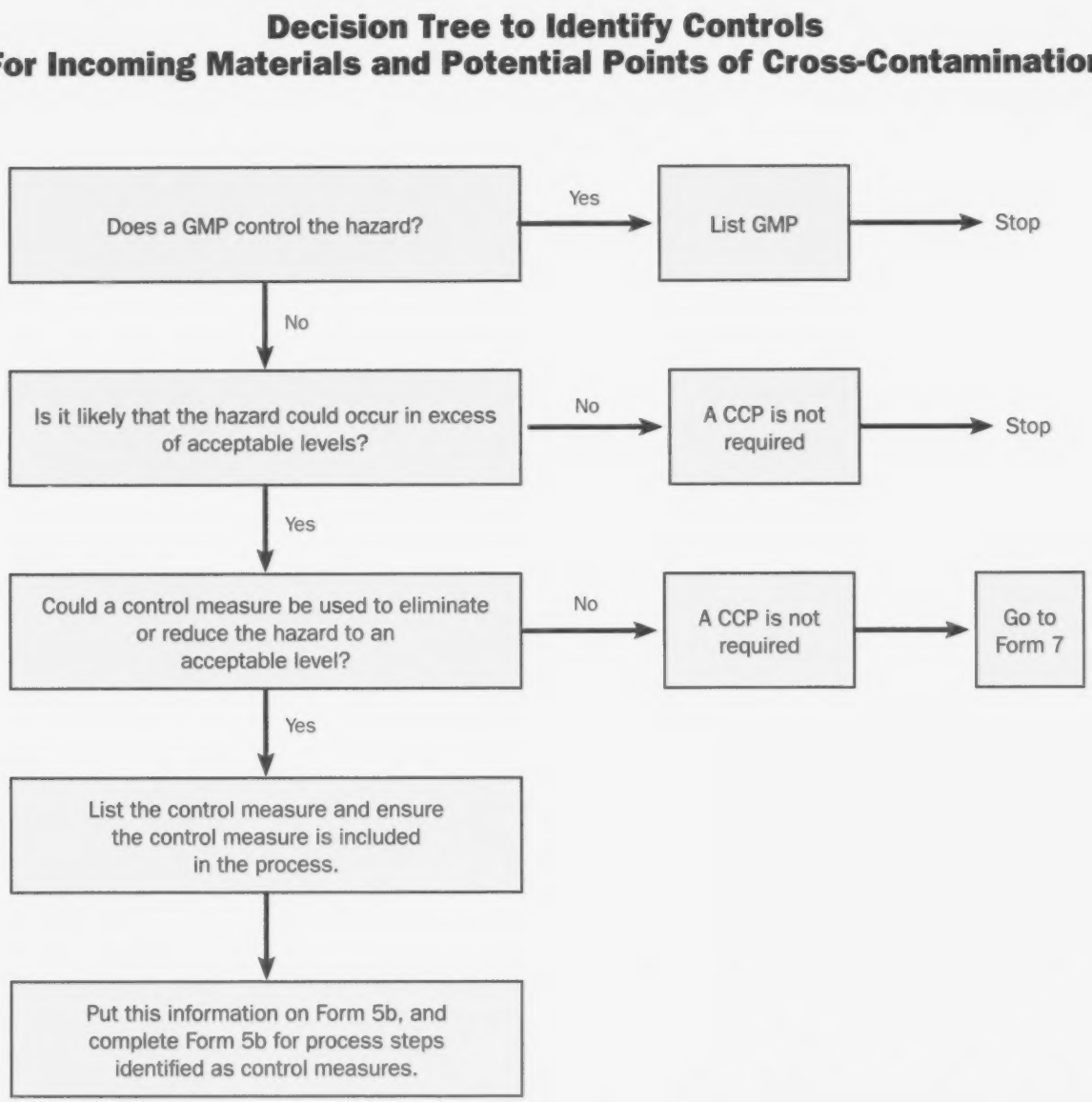


Figure 7. Sample Form 5a

Form 5a: Hazard Description and Control Incoming Materials and Potential Points of Cross-Contamination

Write the plan name that describes all products grouped together in this HACCP Plan.

Plan name: Cooked Sausage Products

Column 1	Column 2	Column 3	Column 4	Column 5
List all: • **incoming ingredients and materials (copy these from Form 2)** • **potential points of cross-contamination (as shown on Form 4)**	**List all biological, chemical and physical hazards associated with:** • **each incoming ingredient and material listed in column 1** • **each potential point of cross-contamination listed in column 1**	**Q1. Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?** **Answer "yes" or "no".** *If "yes", list the GMP program that controls the hazard. Stop. Continue with next hazard.* *If "no", continue to column 4.*	**Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?** **Answer "yes" or "no".** *If "yes", continue to column 5.* *If "no", stop. Continue with the next hazard.*	**Q3. Could a control measure be used to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", list the control measure and ensure the control measure is included in your process, and is identified on Form 5b.* *If "no", list the hazard on Form 7.*
Raw ground beef	B: Contamination with pathogenic bacteria (e.g. *Salmonella* spp., *Clostridium perfringens*, *Campylobacter jejuni*, *Yersinia* spp., *Escherichia coli* O157:H7, *Listeria monocytogenes*)	No	Yes	Yes · cooking
	C: Presence of antibiotics	No	Yes	No
	P: Presence of metallic foreign material	No	Yes	Yes · metal detector
Product flow B3 – Cross-contamination between raw and cooked product.	B: Potential for cross-contamination of cooked product being unloaded from the smokehouse, from raw product ready to be loaded into the smokehouse	Yes · P3.1 Handling & Storage		

Copy each of the ingredients, processing aids and packaging materials that you listed on Form 2, and list them here. Also list potential points of cross-contamination that you identified on Form 4.

Use one row for each item.

Determine, list and describe each biological, chemical and physical hazard associated with each item in column 1.

For potential points of cross-contamination, explain how cross-contamination might occur.

There may be more than one hazard associated with each item.

For each hazard identified in column 2 determine if the hazard is controlled by GMP. Answer "yes" or "no". If a GMP reduces, controls or eliminates the hazard, then there is no need to control it in your HACCP Plan. If a GMP controls the hazard, answer "yes," identify the particular GMP and move to the next hazard. If a GMP does not control the hazard, proceed to the next column.

This column deals with the possibility of the hazard being present in excess of an acceptable level or increasing to an unacceptable level. If the hazard is unlikely to occur at an unacceptable level, then you can answer "no" and move to the next hazard. If, however, the hazard is likely to occur at an unacceptable level then answer "yes" and continue to the next column.

In this column determine if there is a control measure that can be used at any process step to control the hazard. It is possible that you may have to adapt your process to include an appropriate control measure not currently in use. Some hazards cannot be controlled at the facility. Uncontrolled hazards will be listed separately on Form 7.

Form 5b Explanation

Form 5b: Hazard Description and Critical Control Point Determination Process Steps

Plan name:_____

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
List all of the process steps as shown on Form 3.	**List all biological, chemical and physical hazards associated with each process step listed in column 1.**	**Q1. Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?** **Answer "yes" or "no".** *If "yes", list the GMP program that controls the hazard. Stop. Continue with next hazard.* *If "no", continue to column 4.*	**Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?** **Answer "yes" or "no".** *If "yes", continue to column 5.* *If "no", stop. Continue with the next hazard.*	**Q3. Is the process step listed in column 1 designated to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the step is a CCP. Continue to column 8.* *If "no", continue to column 6.*	**Q4. Will a subsequent step eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the subsequent step is a CCP. List the step. Ensure this information is included when you reach that process step on this form.* *If "no", continue to column 7.*	**Q5. Could a control measure be used to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the process must be modified to include the control measure listed in column 5, and then Forms 1, 2, 3, 4 and 5 must be revised to reflect the changes.* *If "no", list the hazard on Form 7.*	**CCP number**

At the top of Form 5b, record the HACCP Plan name.

Column 1: List all of the process steps (as shown on Form 3).

In this column list:

- each process step shown on Form 3, showing both the step number and description (e.g. 1. Receiving)

Copy this information from Form 3 and use one row of Form 5b for each process step.

Column 2: List all biological, chemical and physical hazards associated with each process step listed in column 1.

For each step listed in column 1, use column 2 to list:

- potential biological hazards – e.g. presence and growth of bacteria on surfaces due to improperly cleaned equipment, contamination from poor employee hygiene
- potential chemical hazards – e.g. sanitation residues on equipment due to improper rinsing, allergen cross-contamination due to improper employee handling, excess preservatives added due to improper employee practices or un-calibrated scale
- potential physical hazards – e.g. introduction of flaking paint due to improperly maintained facility, metal contamination due to metal on metal contact

It is possible for each process step to have more than one hazard associated with it. In this case, it may be helpful to subdivide each row using dashed lines. Describe each identified hazard separately – this will help manage the flow of information through the form (see the Sample Form 5a on page 35).

Completing column 2 on Form 5b is almost identical to completing it on Form 5a. It may be possible to determine significant hazards based on knowledge, judgement and experience, or using historical data. There may be cases where it is necessary to use a more formal approach – determining the hazards associated with each process step may require research or external scientific expertise.

To determine the potential biological, chemical and physical hazards, consider consulting one or more of the following resources:

- CFIA Reference Database for Hazard Identification (lists hazards associated with a number of ingredients, processing aids, packaging materials and process steps)
- reference texts
- the latest scientific literature
- historical and known hazards associated with specific process steps
- relevant Codes of Practice
- regulatory requirements or recognised guidelines
- expert determination (e.g. academia, government, industry experts)
- generic models
- food safety consultants
- food processor organizations
- information from equipment manufacturers

When listing each hazard, provide a brief description to explain the hazard and where needed, the potential source. This information will be important when considering control measures to address the hazards.

For example, for a storage step include details such as "pathogen contamination due to damaged packaging or improperly protected product", rather than simply "contamination from pathogens".

Review the Sample Form 5b on page 42 to see examples of how hazards can be described.

Column 3: Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?

This column requires a "yes" or "no" answer. To answer this question, determine if there is a Good Manufacturing Practices (GMP) program to control the hazard listed in column 2.

If there is a GMP program that controls the hazard, record "yes" and list the specific GMP (e.g. P1.1 Personnel Practices). In this case, you don't need to go any further on this form for this hazard once you have listed the GMP – proceed to the next identified hazard. If there is no GMP program capable of controlling the hazard, answer "no" and proceed to column 4.

To answer this question, it is important to understand what is meant by "to a level that will prevent it from compromising the safety of the finished product." Consider the type or level of control a GMP can provide. In some cases there may be a GMP that provides partial control over a hazard but does not fully control a hazard. In other cases, the GMP program will fully control the hazard.

For example, consider the potential for a chemical hazard associated with allergen residues on equipment. Although equipment cleaning and sanitizing is addressed in GMP, the sanitation program is not designed to fully control the removal of trace allergens. So if a facility processes allergen and non-allergen products, the answer is "no" and you continue to column 4 for this hazard to determine how to ensure all allergens are properly labelled on all products.

Similarly, consider a biological hazard that could result due to inadequate cooking times and temperatures at a cooking step. In this case, there is no GMP program specific to the cooking process, so you answer "no" and continue to column 4 for this hazard.

In another example, consider the potential for a chemical hazard associated with cleaning chemical residues on the surface of food processing equipment. This hazard is completely controlled by the Sanitation GMP program and the rest of Form 5b does not need to be completed for this hazard – simply state the GMP program you are relying on and move to the next hazard on this form.

Column 4: Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

This column requires a "yes" or "no" answer. To answer this question, determine and understand what the acceptable levels are. To determine acceptable levels, consult regulatory requirements or industry best practices. If there are no established acceptable levels, it is your responsibility to justify to the auditor during the certification process, how and why you arrived at your answer.

To determine acceptable levels, consider the impact certain levels of the hazard could cause. There may be certain levels of a hazard that do not cause illness or injury, but above those levels the hazard can cause harm. This may be when you need to consider seeking external expert advice (e.g. food safety consultant, academia).

When answering this question, consider the historical compliance of the hazard being analyzed. For instance, have repeated results of micro testing indicated the presence of a pathogen? Have you had repeated problems with a piece of equipment? Have you had to perform a recall due to the hazard?

If your answer to this question is "no", be sure information to justify this decision is available. You may need several pieces of evidence to thoroughly support your claim.

If you answer "yes" in this column, proceed to column 5.

Column 5: Is the process step listed in column 1 designed to eliminate or reduce the hazard to an acceptable level?

This question is asking if the process step listed in column 1 is designed to control the hazard listed in column 2. If the answer is "yes", the step listed in column 1 is a CCP and you can skip to column 8. If the answer is "no", proceed to the next column.

When answering this question, consider not only what the process step was intentionally designed to do, but also what the outcome of the step is. For instance, there may be a step in your process not initially implemented for food safety reasons (perhaps there were quality reasons), but the step also has the ability to control a food safety hazard. For this type of step, answer "yes" in this column.

For example, consider a mixing/formulating step to ensure the proper ratios of each ingredient for a batch of cookies. This step could also be used to ensure only the proper ingredients are added to each batch of each product, controlling the potential for unintentional allergen addition.

Column 6: Will a subsequent step eliminate or reduce the hazard to an acceptable level?

This is also a "yes" or "no" question.

If the step listed in column 1 does not control the hazard, there may be a step later in the process that does control the hazard. If there is a subsequent step to control the hazard, this subsequent step will be a CCP. Remember that CCPs are not necessarily located where the hazard occurs – they may be at a subsequent step.

If the answer is "yes" – and there is a subsequent step to eliminate or reduce the hazard to an acceptable level – that step becomes a CCP. Be sure to include this information at this later step when completing this form.

If the answer is "no" – and there is not a subsequent step to control the hazard – the process may need to be modified. You need to proceed to the next column.

When answering this question, remember the question refers to any process step occurring in the facility as part of the process. The question is not asking about steps that could occur later in the food chain (e.g. consumer cooking).

Column 7: Could a control measure be used to eliminate or reduce the hazard to an acceptable level?

This question is asking if there is any action or activity that can be implemented to prevent or eliminate the hazard, or reduce it to an acceptable level. Consider any control measures that currently exist as part of the process and, if needed, any control measures that could reasonably be expected to be implemented. You may have to adapt your process to include a control measure not currently in use.

The question requires you to answer "yes" or "no". If the answer is "yes", list the control measure and if necessary modify the process. If the process is modified to include a new control measure, then Forms 1, 2, 3, 4 and 5 may need to be revised.

If the answer is "no", list the hazard on Form 7.

Form 7 is used to list hazards that cannot be controlled, and must be controlled elsewhere in the food chain – e.g. pesticide withdrawal times, cooking of raw ground beef by the consumer. A more detailed explanation of Form 7 is on page 45.

Column 8: CCP number.

This column is where you record the number of each CCP that has been determined. The information for this column is determined when you answer "yes" in column 5.

Be sure to number each CCP and indicate what category of hazard it is designed to control. Generally, the first CCP in the process will be "1", and the following CCPs are numbered sequentially (e.g. CCP1, CCP2, CCP3, etc). A "B" for biological, "C" for chemical or "P" for physical is recorded to identify what category of hazard is controlled (e.g. CCP1B would be the first CCP in the process and would control a biological hazard).

Figure 8 shows the questions from Form 5b in a decision tree format.

Figure 8. Decision tree to identify CCPs for process steps

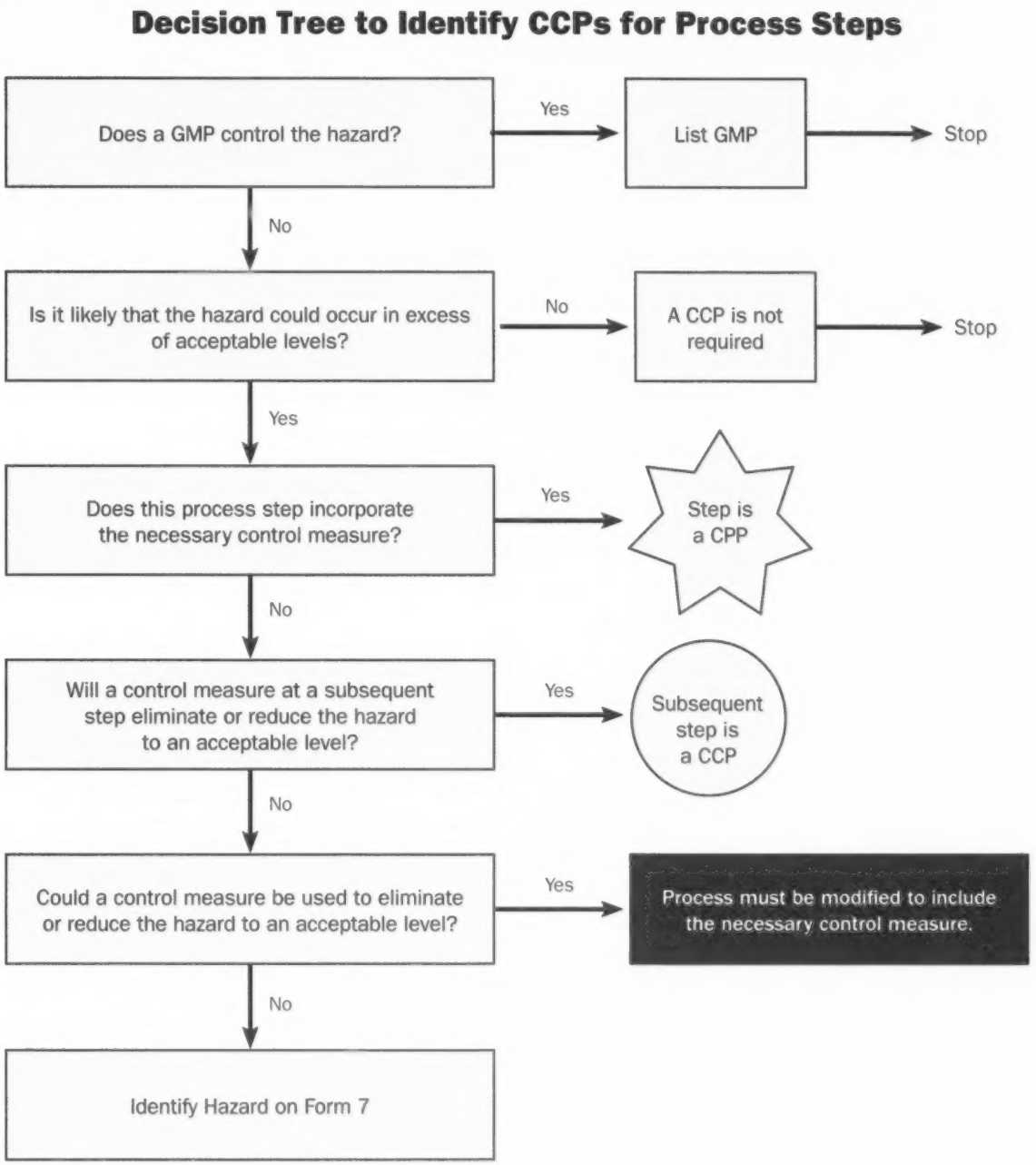


Figure 9. Sample Form 5b

Form 5b: Hazard Description and Critical Control Point Determination Process Steps

Write the plan name that describes all products grouped together in this HACCP Plan.

Plan name: **Cooked Sausage Products**

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
List all of the process steps as shown on Form 3.	**List all biological, chemical and physical hazards associated with each process step listed in column 1.**	**Q1. Does a GMP control the hazard to a level that will prevent it from compromising the safety of the finished product?** **Answer "yes" or "no".** *If "yes", list the GMP program that controls the hazard. Stop. Continue with next hazard.* *If "no", continue to column 4.*	**Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?** **Answer "yes" or "no".** *If "yes", continue to column 5.* *If "no", continue with the next hazard.*	**Q3. Is the process step listed in column 1 designed to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the step is a CCP. Continue to column 8.* *If "no", continue to column 6.*	**Q4. Will a subsequent step eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the subsequent step is a CCP. List the step. Ensure this information is included when you reach that process step on this form.* *If "no", continue to column 7.*	**Q5. Could a control measure be used to eliminate or reduce the hazard to an acceptable level?** **Answer "yes" or "no".** *If "yes", the process must be modified to include the control measure, and Forms 1, 2, 3, 4 and 5 must be revised to reflect the changes.* *If "no", list the hazard on Form 7.*	**CCP Number**
9: Stuffing	C: Chemical contamination from sanitation chemical residues on equipment.	Yes · P4.1 Cleaning & Sanitizing					
10: Cooking	B: Pathogenic bacteria survival if the product is not cooked to minimum internal temperature.	No	Yes	Yes · proper cooking			CCP 1B

Copy each of the process steps shown on Form 3, and list them here. Make sure to include the step number and description. Use one row for each step.

Determine, list, and describe each biological, chemical and physical hazard associated with each item in column 1.

There may be more than one hazard associated with each item.

For each hazard identified in column 2 determine if the hazard is controlled by GMPs. Answer "yes" or "no". If a GMP reduces, controls or eliminates the hazard, there is no need to control it in your HACCP Plan. If a GMP controls the hazard, answer "yes," identify the particular GMP and move to the next hazard. If a GMP does not control the hazard, proceed to the next column.

This column deals with the possibility of the hazard being present in excess of an acceptable level or increasing to an unacceptable level. If the hazard is unlikely to occur at an unacceptable level, then you can answer "no' and move to the next hazard. If, however, the hazard is likely to occur at an unacceptable level then answer "yes" and continue to the next column.

This question is in reference specifically to the step listed in column 1. Is the intent of the step to control the hazard listed in column 2, "yes" or "no"? If "yes", the step is a CCP. If "no", continue to the next column.

This question is asking if there is a process step further down the process flow where this hazard can be controlled. If there is, that step will be a CCP and you must include this later on this form. If there is not a subsequent step, the process may need to be amended. Continue to the next column.

This question is asking if there is a possible control measure that could be used at any process step to control the hazard, even if the control measure isn't currently implemented. If there is, it is possible that you may have to adapt your process to include an appropriate control measure not currently in use. Some hazards cannot be controlled at the facility. Uncontrolled hazards will be listed separately on Form 7.

List the naming convention for each CCP .

Form 6: Flow Diagram with Critical Control Points

Purpose

To show the location of the Critical Control Points (CCPs) in the process.

Importance

Provides an overall representation of the processing steps that are key to ensuring food safety.

How to complete Form 6

At the top of Form 6, record the HACCP Plan name.

To complete Form 6, start with the same flow diagram from Form 3, and simply copy it.

At each process step, use a "B", "C" or "P" to indicate if there is a biological, chemical or physical hazard associated at that step – take this information from Form 5.

Next to each process step where a CCP is located – as determined in Form 5b – identify the CCP. Number each CCP and indicate what category of hazard it is designed to control. Generally, the first CCP in the process will be "1", and the following CCPs are numbered sequentially (e.g. CCP1, CCP2, CCP3, etc). A "B" for biological, "C" for chemical or "P" for physical is recorded to identify what category of hazard is controlled (e.g. CCP1B would be the first CCP in the process and would control a biological hazard).

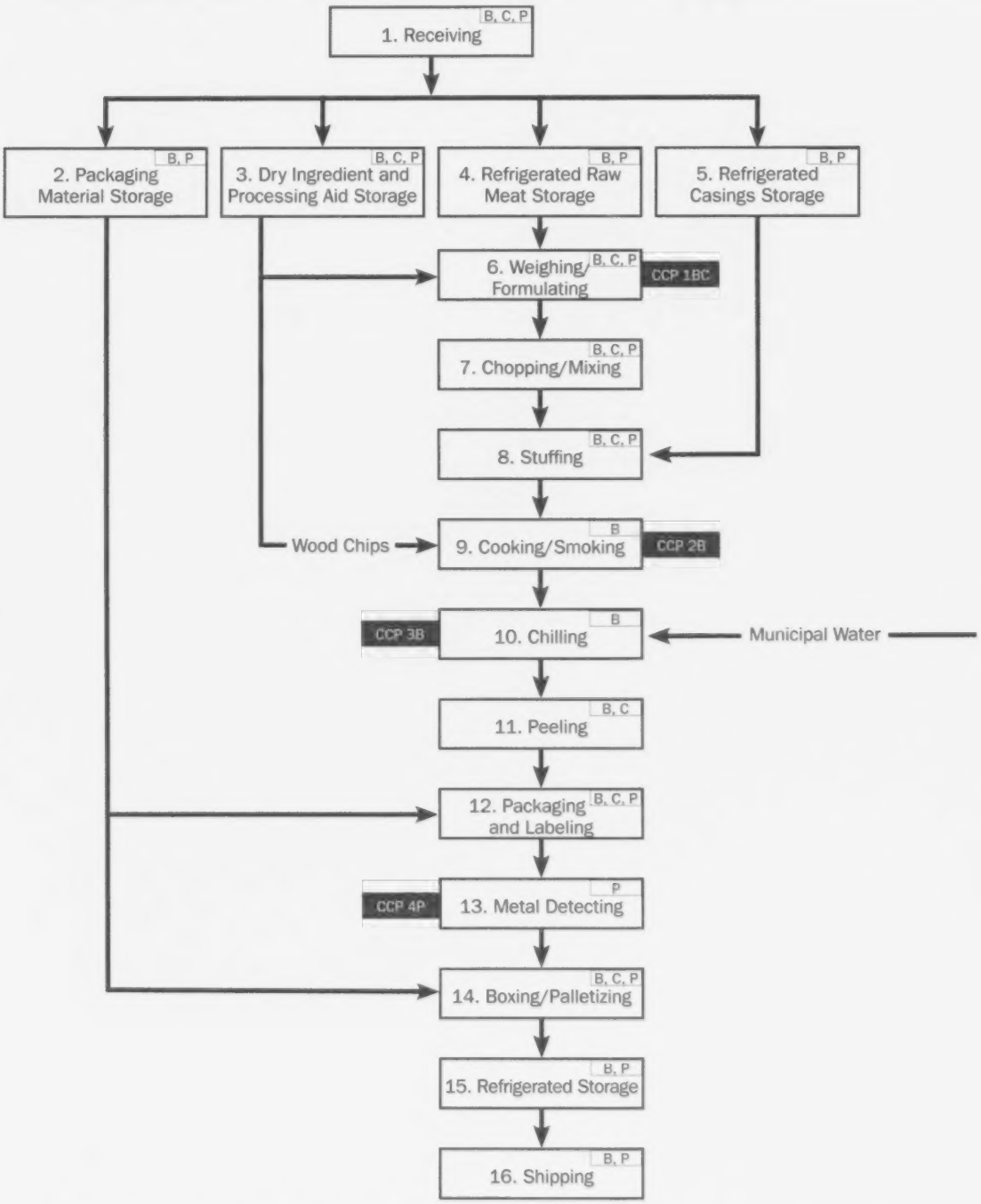
Remember, a new flow diagram does not need to be created. Copy the flow diagram from Form 3, and simply add the location of biological, chemical and physical hazards and the location of the CCPs.

Figure 10. Sample Form 6

Form 6: Flow Diagram with Critical Control Points

Write the plan name that describes all products grouped together in this HACCP Plan.

Plan name: **Cooked Sausage Products**



Form 7: Uncontrolled Hazards

Purpose

To list any hazards that cannot be controlled at the facility through the GMP program and HACCP Plan, and record where these hazards can be controlled in the food chain.

Importance

It is important to understand how other parts of the food chain affect the safety of the product, and to realize not all hazards can be controlled within the facility.

How to complete Form 7

At the top of Form 7, record the HACCP Plan name.

This form has two columns. In the first column, record each hazard not controlled by the process – these hazards are identified in Form 5a, column 5 and in Form 5b, column 7. The question in these columns asked "Could a control measure be used to eliminate or reduce the hazard to an acceptable level." If there was no control measure the processor could reasonably be expected to use, the instructions indicate the hazard should be listed on Form 7.

In the second column, record how the hazard may be controlled elsewhere in the food chain. Generally, hazards are controlled earlier in the food chain (e.g. by the grower or farmer) or later in the food chain (e.g. by the consumer).

For items that require control later in the food chain, ensure appropriate instructions on the label are provided to the user. For instance, a raw meat product may need to be cooked prior to consumption, so cooking instructions are needed.

Write the plan name that describes all products grouped together in this HACCP Plan.

Figure 11. Sample Form 7

Form 7: Uncontrolled Hazards

Plan name: **Cooked Sausage Products**

- Summarize all **biological, chemical** and **physical** hazards in your facility as identified by a "no" answer in:
  - Q3 on Form 5a
  - Q5 on Form 5b
- Indicate how each hazard will be controlled before or after the process (e.g. cooking prior to consumption, farm level Good Agricultural Practices)

Hazards	How the hazard could be addressed
Chemical – meat products (chicken) contaminated with antibiotics	Producer education, good farming practices and compliance with feed withdrawal period(s)
...continued	

Form 8: HACCP Matrix

Purpose

To document, for each Critical Control Point (CCP) in the HACCP Plan, the:

- critical limits
- monitoring procedures
- deviation procedures
- verification procedures

Importance

The HACCP Matrix is where you record details of the control measures for each Critical Control Point (CCP) determined on Form 5b.

The information on this form provides instructions to the people responsible for activities related to each CCP. The HACCP Matrix can also serve as a training tool for employees responsible for CCP monitoring and verification.

How to complete Form 8

At the top of Form 8, record the HACCP Plan name.

Complete one row of the form for each CCP. For each CCP record the following.

Column 1: Process step

Record the process step where the CCP is located. Make sure to record both the process step number and process step name as shown on Form 3. For example "18. Cooking".

Column 2: CCP number

Record the CCP number and its category. Generally, the first CCP in the process will be "1" and the following CCPs are numbered sequentially (e.g. CCP1, CCP2, CCP3, etc). A "B" for biological, "C" for chemical or "P" for physical is recorded next to the CCP number to identify the category of hazard controlled (e.g. CCP1B would be the first CCP in the process and would control a biological hazard).

This information can be copied directly from the last column of Form 5b.

Column 3: Hazard description

In this column, identify whether the hazard is biological, chemical or physical, and describe the hazard the CCP is to control. Hazard descriptions can be copied from the hazards listed in Form 5a and 5b.

Column 4: Critical limits

In this column, record the limits necessary to produce a safe product.

Critical limit

A criterion which separates acceptability from unacceptability. (Codex definition)

A critical limit is the criteria that separate a safe product from a potentially unsafe product.

Critical limits:

- define maximum and/or minimum values for CCP parameters – examples of parameters controlled at a CCP may include internal temperature, time, water activity, chlorine level, salt level, pH
- mark the boundary where a food safety hazard can be prevented, eliminated or reduced to an acceptable level
- must be clearly defined, objective and measurable
- are often determined from sources such as regulatory guidelines and published scientific data

Note: if you are using control measures or critical limits that are novel or unique – and not considered to be an industry standard or best practice – you must demonstrate scientifically that the control measure is effective at controlling the hazard and can eliminate the hazard or reduce it to an acceptable level.

Column 5: Monitoring procedures

For each CCP, document and implement monitoring procedures to ensure critical limits are being met.

Monitor

The act of conducting planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. (Codex definition)

Monitoring procedures must be documented and results must be recorded. Monitoring procedures are performed at predetermined frequencies, and if results show critical limits are not met, the process is out of control and corrective actions must be taken.

Monitoring procedures must include:

- who performs the procedure
- what will be measured or evaluated (e.g. product temperature)
- how the procedure is to be performed (e.g. use of specialized instruments)
- when or how often the monitoring is performed
- where the monitoring results/observations are recorded

Monitoring procedures can also indicate if there is a trend toward loss of control. Even if critical limits are being met, monitoring results can provide early warning signs that the process may eventually be out of control. This provides the opportunity to make adjustments to the process prior to a deviation occurring.

The monitoring procedures you develop must be reliable and reproducible. The instruments you choose must be precise (measure to the detail required) and accurate (measure correctly each time). Ideally, monitoring procedures are performed continuously (i.e. all product is monitored against the critical limit). In reality it is not always feasible or practical to monitor a CCP on a continuous basis.

Balance the frequency of monitoring with practicality – the frequency must be achievable and realistic. If critical limits are not met, you must be able to regain control of all products since the last acceptable monitoring check. All products since the last acceptable monitoring check may be unsafe and must be controlled – e.g. held, potentially recalled or destroyed.

Column 6: Deviations and corrective actions procedures

For each CCP there must be planned, written corrective action procedures. You must describe ahead of time what will be done if monitoring procedures indicate the critical limit is not achieved. Corrective actions are predetermined activities taken when CCP monitoring indicates a deviation has occurred.

Deviation

Failure to meet a critical limit. (Codex definition)

Corrective action

Any action to be taken when the results of monitoring at the CCP indicate a loss of control. (Codex definition)

Corrective actions must identify, locate and control any product processed while the CCP was out of control.

Corrective action procedures must include:

- who performs the procedures
- how the procedure is to be performed (e.g. use of specialized instruments)
- where the observations are to be recorded – this is commonly done on the same record on which the monitoring is recorded

Corrective actions procedures must include measures to:

- regain control of the process
- control all affected product and equipment
- determine the disposition of affected product (appropriate product dispositions may include holding, reworking or destroying)
- determine and correct the root cause of the problem to prevent a reoccurrence of the deviation

The planned corrective actions must be written (i.e. describe ahead of time what you will do when a critical limit is not met) and any corrective actions taken must be recorded. Corrective actions should be taken as soon as possible, and must happen in time to prevent potentially unsafe from product reaching the customer.

Column 7: Verification procedures

For each CCP, document and implement verification procedures to ensure monitoring procedures and corrective action procedures are performed as written.

Verification

The application of methods, procedures and tests, and other evaluations in addition to monitoring, to determine compliance with the HACCP Plan. (Codex definition)

Verification procedures must be documented and results recorded. Verification procedures are performed at a predetermined frequency, but less frequently than monitoring procedures. Verification is commonly referred to as "monitoring the monitor" or ensuring that what the monitor is doing is correct and all issues are properly handled. Verification activities are performed by someone other than the person performing the monitoring (e.g. supervisor, quality assurance staff, HACCP Coordinator).

Verification activities are performed to ensure:

- the monitoring procedures and any required corrective actions are being properly performed
- the appropriate records are being completed

Verification procedures must include:

- who performs the procedure
- what will be measured or evaluated
- how the procedure is to be performed (e.g. use of specialized instruments)
- when or how often the procedure is performed
- where the observations are to be recorded

Verification procedures must also include the corrective actions that are taken if verification procedures indicate that a deviation has occurred. These written corrective actions must include:

- who takes the corrective action
- what procedures are to be followed
- where the actions are recorded

If verification activities are showing repeated deviations, it is an indication that monitoring procedures and deviation procedures may need to be amended.

Column 8: HACCP records

Many records are generated once your HACCP Plan is in place. Records are the "proof" you rely on in an audit or potential food safety crisis, showing that your Plan was functioning effectively and identified hazards were properly controlled. In the last column of the HACCP Matrix, list all records that could be used in relation to the CCP – monitoring records, corrective action records, verification records and any other records pertinent to the CCP.

Reviewing HACCP Plans

Once your HACCP Plan(s) are developed and implemented, you need to continue to maintain and update the Plan(s).

At least once a year – or when changes are made – the HACCP coordinator is required to update components of the HACCP Plan including associated monitoring records, procedures, etc. When changes occur, be sure they are recorded in a log book. The log book is used to control the dates and reasons for changes made to the HACCP Plan and provides a history of the program updates. GMP and HACCP changes/updates can be recorded in the same log book (see the "Program Review" standard in *Advantage GMP* Book 2).

It is necessary to review your HACCP Plans – making any necessary changes – when the following occur:

- change in raw materials, ingredients, processing aids or their suppliers of raw materials
- change in ingredients or recipe
- change in process steps or equipment
- change in packaging materials or storage conditions
- change in consumer use
- developments in scientific research associated with ingredients, products or processes
- negative trends based on customer complaints, product recall

Figure 12. Sample Form 8

Write the plan name that describes all products grouped together in this HACCP Plan.

Form 8: HACCP Matrix

Plan name: **Cooked Sausage Products**

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Process step Number and description as shown on Form 3.	**CCP number** Number sequentially	**Hazard description** Identify whether the hazard is biological, chemical or physical. Describe hazard.	**Critical limits** Define the value(s) that are acceptable to maintain the CCP under control.	**Monitoring procedures** Identify the following: • who is responsible for the task • what procedure is to be followed • what observation is to be made or what measurement is to be taken • how often the task is to be performed • where the observations are to be recorded	**Deviations and corrective action procedures** If monitoring indicates a deviation, describe: • who takes the corrective actions • what procedures are to be followed • where the actions are to be recorded	**Verification procedures** Identify the following: • who is responsible for the task • what procedure is to be followed • what observation is to be made or what measurement is to be taken • how often the task is to be performed • where the observations are to be recorded If verification indicates a deviation describe: • who takes the corrective actions • what procedures are to be followed • where the actions are to be recorded	**HACCP records** List records to be used
10. Cooking	CCP 2B	B: Contamination with pathogenic bacteria (e.g. *Salmonella* spp., *Clostridium perfringens, Campylobacter jejuni, Yersinia* spp., *Escherichia coli* O157:H7, *Listeria monocytogenes*).	Product must be cooked to a minimum internal temperature of 70°C.	**Who:** The Smokehouse Operator **What/When:** Take the internal temperature of one hot dog from each of rows 5, 10 and 15 at the end of every cook cycle to ensure the product has reached a minimum internal temperature of 70°C.	**Who:** The Smokehouse Operator **What/When:** If the minimum internal temperature of 70°C has not been reached, notify the HACCP Coordinator immediately.	**Who:** The HACCP Coordinator **What/When:** **1.** Once per day review the Cook Production Records to ensure that critical limits were met, that the records were properly completed, and that deviations and corrective actions were recorded when required.	Cook Production Record Hold Record

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
				How: With a calibrated hand-held thermometer. **Records:** The Smokehouse Operator will record temperatures, date, times and initials on the Cook Production Record, and will complete all other necessary sections of the record.	**Records:** The Smokehouse Operator records all deviations and corrective actions on the Cook Production Record. **Who:** The HACCP Coordinator **What/When:** When notified by the Smokehouse Operator that the critical limits were not met, place all products since the last passed check on hold and ensure they are re-cooked until the critical limit is met. If the critical limit cannot be met, condemn the products and ensure all affected products are properly disposed of. Investigate the root cause of the deviation and implement an action plan to prevent a reoccurrence. **Records:** The HACCP Coordinator records all corrective actions on the Cook Production Record. The HACCP Coordinator also completes, dates and signs the Hold Record.	**2.** Once per week observe the monitoring of the cooking CCP to ensure it is monitored as written in the monitoring procedures. **3.** If deviations are found during daily or weekly verification activities, determine if food safety has been compromised. If so, product will be placed on hold and a food safety assessment performed. Investigate the root cause of the deviation and implement an action plan to prevent a reoccurrence. **Records:** **1.** The HACCP Coordinator signs and dates the Cook Production Records in the daily verification section. **2.** The HACCP Coordinator signs and dates the Cook Production Record in the weekly verification section. **3.** The HACCP Coordinator records deviations and corrective actions on the Cook Production Records, and signs and dates the records. The HACCP Coordinator also completes, dates, and signs the Hold Record.	

Figure 13. Sample CCP record – CCP monitoring and verification record for cooking

CCP record – CCP monitoring and verification record for cooking

ABC Sausage Company Cook Production Record – CCP 2B

Smokehouse Operator name: _____ Date: _____

Critical limits: Product must be cooked to a minimum internal temperature of 70°C (158°F).
Corrective action: Inform the HACCP Coordinator if minimum internal temperature is not reached.

Time	Batch #	Product name and product code	Internal product temperature reading from hand held thermometer			Deviation	Corrective actions by Smokehouse Operator	Date and time	Initials	Corrective actions by HACCP Coordinator	Date and time	Initials
			Row 5	Row 10	Row 15							

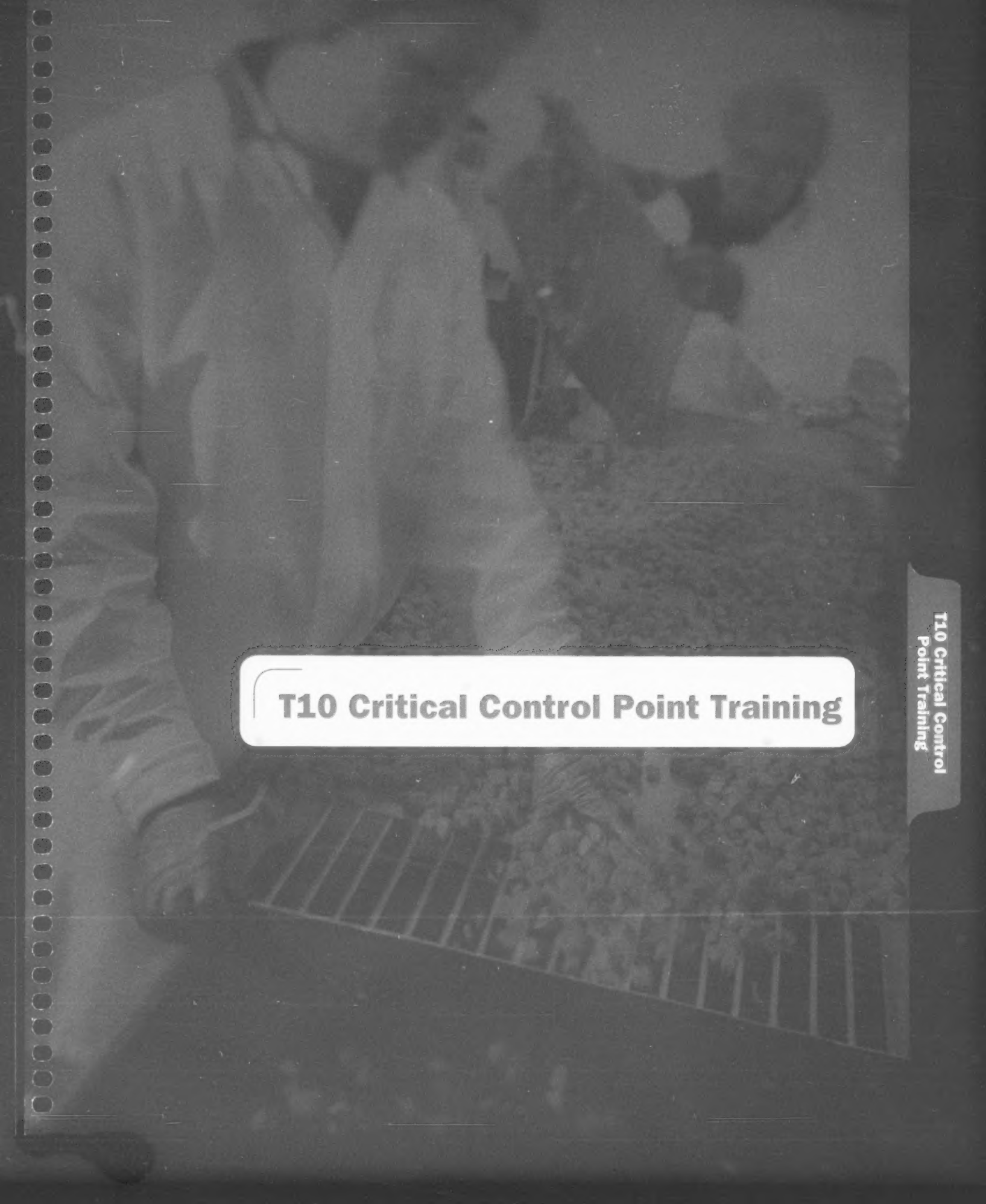
Daily verification activities by HACCP Coordinator	Yes or No	Deviation	Correction actions
Record properly completed, critical limits met, deviations and corrective actions recorded when required.			

Signature: _____ Date: _____

Weekly verification activities by HACCP Coordinator	Yes or No	Deviation	Correction actions
Visually observe that monitoring procedures are performed as written in the HACCP Plan.			

Signature: _____ Date: _____

Created by: Robyn Stevens Creation date: February 14, 2009 Code: RCD CCP2



T10 Critical Control Point Training

T10 Critical Control Point Training

Now that you have finished your HACCP Plan(s), there is one last standard to complete – the standard for training employees responsible for CCP activities. This last standard is called "T10 Critical Control Point Training".

This standard for CCP training is not included in the *Advantage GMP* program because it applies only to facilities that have implemented *Advantage HACCP* and identified CCPs. Without a HACCP Plan, there is no need for CCP training.

This standard ensures that employees responsible for CCPs receive the necessary training. This training is important because CCPs are designed to control hazards that cannot be controlled by the GMP program. If CCP activities are not properly performed, the safety of the food is compromised.

Remember to include this CCP training standard as part of your Training Program Review Standard in your GMP program. The training program review standard is designed to ensure your training program is up-to-date and reflects current written programs. For more information, see *Advantage GMP* Book 2.

You can also include CCP training in the training schedule developed as part of your GMP program – to help you remember to provide CCP training at the appropriate frequency.

Note: This training standard is set up exactly as all other *Advantage GMP* standards. The standard is presented in the blue box at the top of the page, and the suggestions to meet the standard are presented below.

Critical Control Point Training T10

Written procedures and corresponding records are in use for training on all Critical Control Points (CCPs) for each HACCP Plan as written on the HACCP Matrix (*Advantage HACCP* Form 8). The procedures identify:

- employees who require training
- who performs the training
- training material used
- frequency of training
- assessment method to confirm the training is understood

Training is provided prior to performing CCP duties, whenever changes are made to CCPs, and refresher training is provided at minimum once per year.

Suggestions to meet the standard

Training material for each CCP should address:

- critical limits
- monitoring procedures to check that critical limits are met
- deviation procedures and corrective actions to be taken if critical limits are not met
- verification procedures to check that monitoring is being performed correctly and records are complete
- deviation procedures and corrective actions to be taken if monitoring procedures are performed incorrectly
- all information and activities contained in the HACCP Matrix (*Advantage HACCP* Form 8)

Some examples of training material that can be used for CCPs include:

- *Advantage HACCP* Form 8/HACCP Plans
- standard operating procedures for specialized processing equipment
- laboratory testing procedures
- hands on processing/monitoring demonstration
- equipment manufacturer's training course

Develop corresponding training records for training material presented:

- training records list who is in attendance, the date the training took place, the topic, the material used, and the name and signature of the trainer
- ensure the list of employees is current (i.e. cross reference with payroll employee list)
- training records have a place for employees to initial or sign to indicate that they received the training

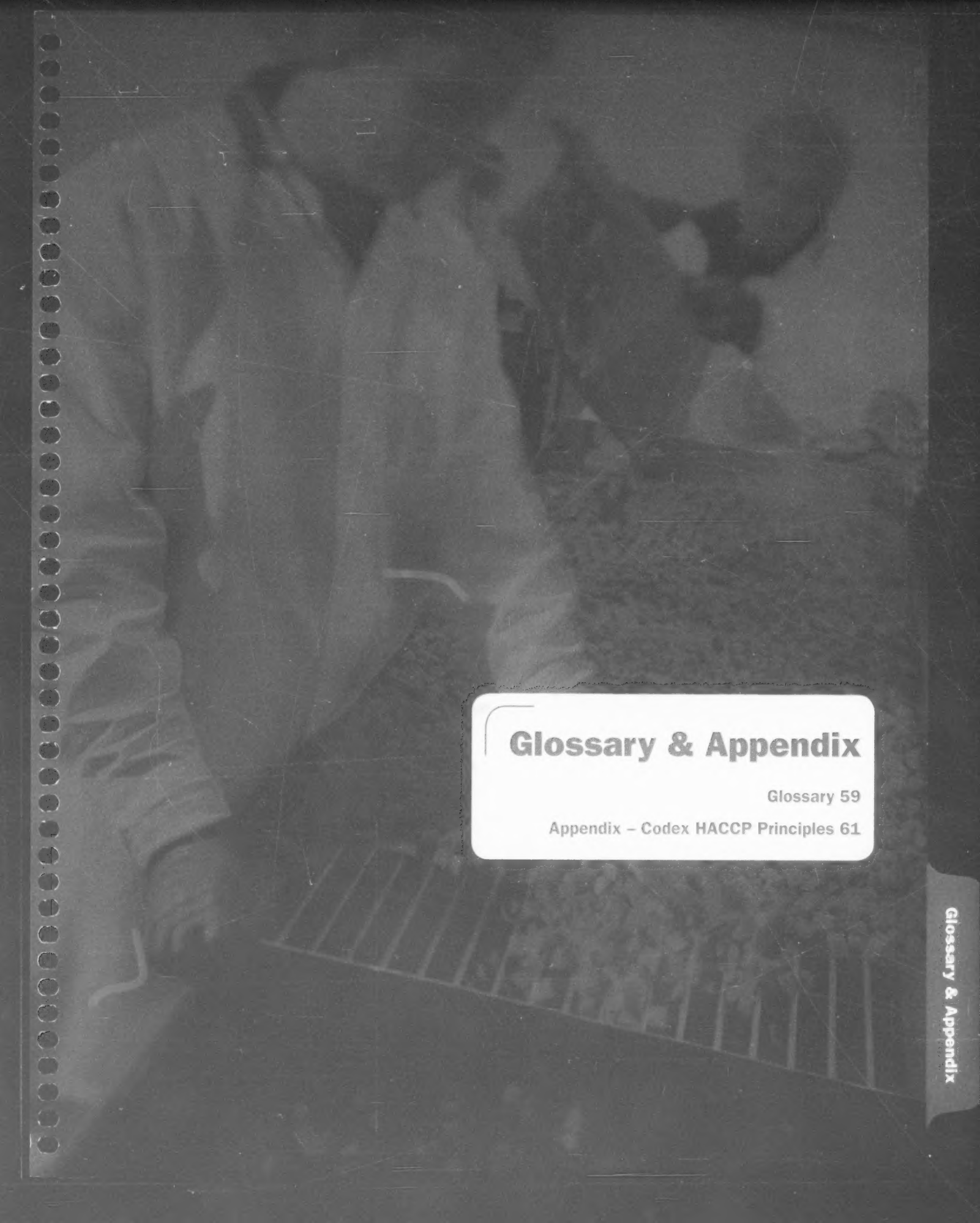
Develop a method to prove that employees who were trained understood the training material. For example a written or verbal test, observe the task being performed or job shadowing for a probation period, etc.

Develop a training schedule:

- the training schedule should include the employees (and their alternate backups) designated to conduct CCP activities and their positions
- the training schedule is predetermined and indicates who needs to be trained and how often refresher training will occur
- CCP training could be included in your GMP training schedule – how often refresher training occurs depends on your process, commodity, turnover rate and/or season of production, e.g. once per year, once per season or every six months

Refresher training should occur any time modifications are made that have an impact on the CCP, i.e. new equipment, modifications to processing, changes to critical limits, changes to HACCP Plan that impact Form 8, etc.

Refresher training may be required if verification finds reoccurring deviations with monitoring procedures or records, e.g. employee not completing records properly, observation of employee incorrectly performing monitoring procedures, etc.



Glossary & Appendix

Glossary

Allergen – a substance that causes some individuals to experience an immune system response, such as an allergic reaction.

a_w (water activity) – a measure of the free water available, in a food, for biological or chemical reactions.

Biological hazard – any micro-organism or toxin produced by a micro-organism that can cause food-borne illness when ingested.

CCP (Critical Control Point) – a point, step or procedure at which a control measure can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

CCP decision tree – a sequence of questions used to determine where CCPs are located.

Chemical hazard – any chemical agent that may cause injury or illness when ingested or inhaled.

Codex Alimentarius Commission – a commission set up by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) of the United Nations to develop internationally recognized food standards, guidelines and related texts such as codes of practice.

Consumer Packaging and Labelling Act – a federal act that provides for a uniform method of labelling and packaging of consumer goods as well as prevention of fraud and deception by provision of factual label information.

Corrective actions – measures taken to regain control of a hazard, to determine the disposition of affected product and to prevent a reoccurrence of the problem.

Critical limits – the maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.

Cross-contamination – the physical movement, or transfer, of harmful micro-organisms, allergens, chemical contaminants, or any foreign substance from one person, object, food or place to another.

Deviation – failure to meet a HACCP system requirement.

Facility schematic – diagram showing where each step of the manufacturing process occurs within the facility.

Flow diagram – a systematic representation of the sequence of steps or operations used in the processing of a particular food.

Food and Drugs Act – a federal act that establishes regulations regarding food, drugs, cosmetics and therapeutic devices.

GMP (Good Manufacturing Practices) – practices, policies and procedures that promote effective hygiene and the processing of safe food.

HACCP coordinator – a person designated to oversee the development, implementation and maintenance of the HACCP system.

HACCP plan – a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

HACCP principles – seven principles (or steps) that are standardized by the Codex Alimentarius Commission for the development of a HACCP Plan.

HACCP system – A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP team – the group of people involved in the development, implementation and maintenance of the HACCP system.

Hazard analysis – the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP Plan.

Immuno-compromised – individuals who may be more susceptible to food-borne illness due to a deficiency in their immune response.

Monitoring – the process of conducting a planned sequence of observations or measurements to determine if a prerequisite program or CCP is under control.

Pathogen – a micro-organism that can cause illness or disease in humans.

pH – a way of expressing the acidity or alkalinity of substances. It is expressed on a scale from 0 to 14, where 0 is extremely acidic, 7.0 is neutral and 14 is extremely alkaline.

Physical hazard – any material in food that could cause injury or illness.

Processing aid – a substance used in the processing of a food product that is not present in the final product.

Salinity – a measure of the salt concentration.

Uncontrolled hazard – a hazard that cannot be controlled by a facility's HACCP system.

Validation – process of obtaining evidence that the elements of the HACCP system are effective.

Verification – the application of methods, procedures, tests and other evaluation, in addition to monitoring to determine compliance with the HACCP Plan.

Appendix – Codex HACCP Principles

HACCP Plans are developed using 12 steps, which incorporate the seven principles of HACCP, standardized by the Codex Alimentarius Commission.

1. Assemble HACCP Team

The HACCP team should be multidisciplinary, representing individuals from all areas of the facility.

2. Describe Product

A full description of each product is required, including all relevant safety information.

3. Identify Intended Use

The intended use is based upon the expected uses of the product. If the product is destined for vulnerable population groups, this needs to be identified (e.g. elderly, immuno-compromised).

4. Construct Flow Diagram

Draw a flow diagram that shows all the steps in the manufacturing process for a specific product.

5. On-site Confirmation of Flow Diagram

Steps must be taken to verify the diagram is accurate. Confirmation of the flow diagram against actual operations should occur for each step and at all hours of operation. The diagram should be amended as required.

6. Principle 1: Conduct a Hazard Analysis

Identify all of the hazards that may be reasonably expected to occur. Then determine which hazards are significant to food safety and must be addressed in the HACCP Plan.

7. Principle 2: Determine the Critical Control Points (CCP)

Identify where in the processing operation the hazards addressed in the HACCP Plan can be prevented, reduced or eliminated.

8. Principle 3: Establish Critical Limits

Critical limits must be established for each CCP. Critical limits are criteria that separate safe product from unsafe product. Critical limits must be clearly defined and measurable.

9. Principle 4: Establish Monitoring Procedures

Monitoring is the process of conducting a planned sequence of observations or measurements of a CCP relative to its critical limits. Monitoring procedures must be planned and documented for each CCP.

10. Principle 5: Establish Corrective Actions

Corrective actions are predetermined activities taken when CCP monitoring results indicate a deviation has occurred. For each CCP there must be planned and documented corrective actions.

11. Principle 6: Establish Verification Procedures

Verification activities are used to determine if the HACCP system is working correctly. Verification activities must be planned and documented for each CCP.

12. Principle 7: Establish Record-keeping and Documentation Procedures

HACCP Plans, including all of the items listed above, must be documented. Accurate record keeping is required for the HACCP system.

www.ontario.ca/haccp